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Self-Awareness And Its Association With Functional Performance In Sub-Acute Stroke: A Cross-Sectional Study

Louise Mairead O'Regan
Royal College of Surgeons in Ireland, louisemoregan@rcsi.ie

SELF-AWARENESS AND ITS ASSOCIATION WITH FUNCTIONAL PERFORMANCE IN SUB-ACUTE STROKE: A CROSS-SECTIONAL STUDY

Louise O'Regan, BSc. Occupational Therapy

A dissertation submitted in partial fulfilment of the requirements for the degree of MSc. in Neurology & Gerontology.

School of Physiotherapy,

Faculty of Medicine and Health Sciences,

Royal College of Surgeons in Ireland.

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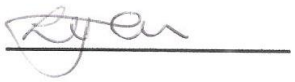
Supervisor: Dr Helen French

Candidate Thesis Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a Master of Science in Neurology and Gerontology is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

Signed: 

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SUMMARY

Introduction

Awareness is the key to successful stroke rehabilitation and in practice poor knowledge of self-awareness and failure to recognise stroke deficits hinders efforts in the rehabilitation of patients. Stroke is associated with both functional and cognitive impairment, but the individual correlation between impairment, daily activities and self-awareness of deficit of stroke patients in the acute and sub-acute environment has yet to be explored. This research study aims to address the gap in the current evidence base, by identifying the degree of patient's self-awareness of stroke-deficit in a sample of patients with sub-acute stroke and determine the strength of relationship between self-awareness and functional performance.

Aim and Objectives

The primary aim of this research was to examine the association between self-awareness and functional performance deficits across three domains (Basic ADL; Instrumental ADL and Cognition) in sub-acute stroke.

The objectives were:

1. To identify patients' self-awareness of stroke-deficit within three months of stroke.
2. To investigate the association between functional outcomes of ADL performance and self-awareness.

Methods

A cross sectional study using a sample of convenience was completed. Nineteen participants admitted to an acute hospital with first event stroke were assessed for awareness of deficit post stroke. Self-awareness was measured using the Self-Regulation Skills Interview (SRSI). A range of outcome measures were used to assess functional and cognitive performance. They included the Modified Barthel Index (MBI), Kettle Test (KT), Montreal Cognitive Assessment (MoCA), Frontal Assessment Battery (FAB).

Results

The majority of participants presented with right sided stroke infarct of mild severity (74%). The majority of participants presented with low-moderate levels of awareness (53%) and were female (58%). Significant correlations were demonstrated between the SRSI, MoCA and KT. The strongest correlation was found between the SRSI and the MoCA ($r= -0.814$), with a strong relationship also demonstrated between the SRSI and the KT ($r=0.521$). There was no relationship between the SRSI and the MBI ($p=0.951$; $r=-0.015$). The association between functional performance outcome measures and other variables was further examined using linear regression analysis. The SRSI explained no variance on the MBI (0%), however explained 23.3% variance on the Kettle Test.

Conclusion

More than half of the participants in this study presented with only low-moderate self-awareness levels of stroke deficit. There was a strong association between self-awareness, cognition and one component of IADL performance as measured on the KT. No correlation was demonstrated between SRSI and MBI.

Implications of Findings

Self-awareness deficits are prevalent in the mild sub-acute stroke population. There is a high association between self-awareness, cognition and higher order activities of daily living (IADL). Screening of mild stroke patients for awareness deficits should be included as a standard measure of care. Future research should address the development of a stroke-specific measure of awareness and standardisation of assessment.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

ADL	Activities of Daily Living
BADL	Basic Activities of Daily Living
CI	Confidence Interval
DADL	Domestic Activities of Daily Living
FAB	Frontal Assessment Battery
IADL	Instrumental Activities of Daily Living
IQR	Interquartile Range
KT	Kettle Test
MBI	Modified Barthel Index
MoCA	Montreal Cognitive Assessment
MS	Multiple Sclerosis
n	Number
r^2	Co-efficient of determination
SD	Standard Deviation
SRSI	Self-Regulation Skills Interview
SSSS	Scandinavian Stroke Severity Scale
TBI	Traumatic Brain Injury
WHO	World Health Organisation

INTRODUCTION

Stroke is a leading cause of disability in all countries, with the prevalence of stroke-related burden expected to increase over the next two decades (Langhorne et al., 2011). Stroke can result in a variety of physical, cognitive and neuro-behavioural impairments and it is well documented in the literature that rehabilitation plays an important role in the functional recovery of stroke patients (Gustafsson et al., 2012). Impaired self-awareness has received particular attention from rehabilitation therapists due to its strong association with motivation for treatment and long-term functional outcome (Al Banna et al, 2015). While many patients recover ambulatory function post stroke, cognitive and awareness deficits have received less attention in relation to stroke recovery. Impairments in cognitive function in the acute phase of stroke have been reported in up to 50% of patients (Chung et al, 2013). However, subtle cognitive deficits remain undetected with particular vulnerability in the mild stroke population (Wolf et al, 2013).

Self-awareness is a complex construct comprising cognitive, behavioural and psychosocial components (Toglia and Kirk, 2000). Most published literature has investigated self-awareness impairment in the post-acute TBI population, with reported prevalence of awareness deficits in this population of up to 97% of cases (Sherer et al, 1998). Impaired self-awareness presents as difficulty recognising impairments, the implications of these impairments and ultimately poor compensation for deficits including difficulty with goal setting in therapy (Fleming and Ownsworth, 2006; Ownsworth and Clare, 2006). The prevalence of awareness deficits in the mild

stroke population is uncertain, with studies reporting incidence of up to 73% (Hartman-Maeir, 2003) in the moderate to severe stroke severity population.

Duits et al. (2008) has reported on the substantial difficulties that challenge stroke patients with awareness deficits particularly relating to functional activities of daily living. Research indicates that patients demonstrate greater impaired self-awareness of cognitive and behavioural impairments than of physical deficits (Prigatano et al., 1990; Sherer et al., 2003). Authors have reported on the impact of self-awareness deficits on access to rehabilitation services, outcome of the rehabilitation process and importantly secondary stroke prevention (Hibbard et al, 1992; Duits et al. 2008; Wolf et al. 2013). Attention needs to be given to patients who fail to address or acknowledge stroke deficits. The absence of complaint does not indicate lack of impairment (Duits et al. 2008). It may be indicative of a self-awareness deficit. If patients are unaware of any given impairment, it may jeopardise their ability to maximise therapy aimed at the amelioration of these impairments. Debate continues about the assessment, content and exact timing of rehabilitative therapy for awareness deficits, however the literature does strongly endorse the early assessment of self-awareness and the provision of meaningful, high-intensity cognitive rehabilitation for recovery from awareness deficits (Skidmore et al., 2011; Liu et al., 2014).

There has been no consensus on the definition or use of standardised measures for the assessment of self-awareness in the stroke population. This study will discuss the mechanisms and principles of self-awareness post stroke in relation to models of self-awareness and the impact of self-awareness deficits on functional performance. It will

highlight therapeutic activity approaches in the remediation of awareness deficits after stroke, while reviewing the latest findings and emerging concepts relating to improving functional task performance. Use of a relatively simple, convenient self-awareness measure, would help identify individuals with awareness deficit, thus allowing them to access appropriate rehabilitation strategies and services. Despite evidence in support of early rehabilitation intervention for stroke patients, the majority of the literature in relation to self-awareness deficits relates to stroke in the chronic phase of illness. Descriptions of awareness following stroke are largely observational in nature, without association to functional and cognitive performance. To date, the prevalence of awareness deficits in the acute and sub-acute stroke population has not been well researched. No study has been identified by the author that has investigated the correlations among self-awareness deficit, cognitive and functional performance in the acute and sub-acute stroke population. A greater understanding of the relationship between self-awareness and cognitive and functional performance in the acute and sub-acute stroke population is necessary to enhance clinical decision-making concerning the need for awareness interventions and the possibility of tailoring therapeutic approaches according to individual circumstances.

CHAPTER 1 LITERATURE REVIEW

1.1 Clinical manifestations of stroke

Stroke is a global healthcare problem and leading cause of disability (Wolfe, 2000), affecting cognitive, perceptual, motor and language abilities of individuals to varying degrees (Langhorne et al., 2009). Therapeutic advances have reduced mortality rates during the acute stages of stroke, however patients continue to experience varying degrees of neurological disability (Goldstein, 2007). Motor deficiency is a leading cause of disability following stroke and the main target of neuro-rehabilitation, however the co-existence of certain cognitive and psychological deficits may impede overall outcome (Jehkonen et al., 2006). Eskes et al. (2009) have reported up to 73% of stroke survivors have functionally significant cognitive deficits in the first months of stroke recovery; with unawareness of these deficits having a detrimental effect on rehabilitation and overall quality of life (Orfei et al., 2009).

1.2 Self-Awareness

1.2.1 Definition

Self-awareness represents a complex neuropsychological concept, and is defined as 'the ability to consciously process information about ourselves in a manner that reflects a relatively objective view while maintaining our unique phenomenological or subjective sense of self' (Prigatano, 1997 pg 301). Throughout the history of unawareness syndrome research, multiple terms are used interchangeably to describe the constructs associated with impaired self-awareness. Anosognosia, lack of insight, unawareness of deficits and denial have all been used to refer to organically based and

psychologically based unawareness phenomena (Prigatano, 1998). Some authors reserve the term anosognosia for describing unawareness of physical deficits alone (Arnadottir, 2004; Bach et al., 2006); while others consider that it manifests itself as diminished insight of a specific deficit in motor, sensory, cognitive, perceptual or behavioural functioning (Orfei, 2007; Prigatano, 2009). It is important to differentiate between the phenomena of impaired awareness (a neurologically based deficit) and denial as they may have a differential impact on rehabilitation (Prigatano, 1996). Impaired self-awareness occurs due to a number of neuroanatomical impairments as well as cognitive deficits, while denial is a psychological defence to preserve self-image and prevent psychological distress (Godfrey et al., 1996). The concept of self-awareness is broad and multifaceted (Nurmi et al., 2014) and indeed difficult to measure (Simmond and Fleming, 2003). However, theoretical frameworks assist in the understanding of the phenomenon.

1.2.2 Conceptual Models of Self-Awareness

Although there are few comprehensive clinical models to conceptualise self-awareness, of those that have been proposed most identify a trio of abilities (Long et al., 2014). Crosson et al. (1989) conceptualised self-awareness as a hierarchical structure by developing the Pyramid Model of Self Awareness. It described self-awareness with three concurrent and independent levels: intellectual awareness, emergent awareness and anticipatory awareness. Intellectual awareness is the foundation level, and it refers to the ability to understand that a difficulty is experienced, which has an implication on daily living (Leung and Liu, 2011). Emergent awareness, at the second level, is the ability to recognise a problem as it is

occurring without receiving feedback. Within this model, intellectual awareness is a prerequisite for emergent awareness. The highest level in the pyramid is anticipatory awareness, which is the ability to anticipate that a problem is going to happen because of impairment. This model emphasises that self-awareness is not a single concept but rather a multidimensional one. Impaired self-awareness manifests as difficulty recognising impairments, understanding the implications of these impairments and ultimately setting realistic goals for the future (Fischer et al., 2004; Ownsworth et al., 2006).

Toglia and Kirk (2000) further developed this framework to distinguish intellectual or 'metacognitive' awareness from emergent or 'online' awareness. This model expands on the work of Crosson et al. (1989) to view metacognitive awareness as an overall knowledge of a disorder. Toglia and Kirk (2000) describe higher level or 'online emergent awareness' as the ability to recognise errors as they transpire and 'online anticipatory awareness' as the ability to anticipate problems before they occur (Toglia and Kirk, 2000). In addition to the anticipatory and emergent awareness model described by Crosson et al. (1989), Toglia and Kirk (2000) define online awareness as including ongoing monitoring and regulation of the task or situation. It includes the concept of understanding, self-monitoring and the awareness of difficulties that own performance could lead to, while developing solutions to these difficulties. Toglia and Kirk (2000) emphasized that there is a dynamic relationship between metacognitive knowledge and online awareness. Whether these aspects of awareness interact in a hierarchical manner is currently under debate (Abreu et al, 2001; Abu-Akel et al., 2011), however research has demonstrated little correlation between intellectual

awareness and on-line emergent awareness but strong association between the two 'online' components (O'Keeffe et al., 2007).

1.2.3 Self-awareness deficit post stroke

Unawareness following stroke can vary in severity and may be domain specific (Bisiach et al., 1986), with research findings demonstrating that it is a multifaceted syndrome with several subtypes for hemiplegia, visual field defect, memory loss, neglect and aphasia (Prigatano, 2009). Awareness deficits are frequently observed in patients with stroke, however have been mostly studied in rehabilitation settings and consequently usually include patients with stroke who have considerable disabilities (Boosman et al., 2014). Wolf et al. (2013) reported vulnerability in patients with milder symptoms post stroke; that despite enduring cognitive impairment including awareness deficits, patients are often discharged home within days and are not typically referred to a rehabilitation programme or other forms of follow-up care for these types of deficits. Prigatano (2009) also described the vulnerability of this population group and associated impaired self-awareness in the acute setting with poorer overall functional outcome.

Cocchini et al. (2012) and Orfei et al. (2009) have reported that to gain a complete profile of unawareness, it is essential to take account of both verbal and non-verbal forms of the phenomenon so that any dissociation between explicit (metacognition) and implicit (online) knowledge can be distinguished. These authors advised that separate domain scores for different ability or functions should be kept in order to capture any modality specificities and to account for the variation in type and severity

of unawareness. The occurrence of unawareness varies widely in the literature depending on the assessment methods used, the patient sample and subtypes of unawareness (Jehkonen et al., 2006) however, literature is limited in the sub-acute stroke population.

1.3 Domains of self-awareness

1.3.1 The interface between self-awareness and ADL Performance

Motor deficiency is the leading cause of disability following stroke however, the co-existence of unawareness often impedes rehabilitation methods (Fotopoulou, 2010). Throughout the past decade a key area of focus in the study of impaired awareness has related to motor deficit impairment. The prototypical form of unawareness is 'anosognosia for hemiplegia' (AHP), the apparent inability to understand or acknowledge contralesional paralysis (Ellis and Small, 1997). Some patients fail to recognise or acknowledge the severity of their motor deficits (Orfei et al., 2007); while others acknowledge the presence of a motor deficits at an explicit level, however are implicitly unaware and attempt to perform standard physical tasks which are impossible (Hartman-Maeir et al., 2001).

A significant amount of research relating to anosognosia for motor impairment, focuses on its association with unilateral neglect. In a population based study, Pederson et al. (1996) reported a prevalence of 21% for anosognosia for motor impairment for hemiplegia and hemianopia in the acute stage of stroke. Appelros et al. (2002) reported similar prevalence of 17% for anosognosia in a community based

stroke incidence study. They reviewed the incidence of neglect and anosognosia and their impact on overall disability post stroke. Appelros et al. (2002) reported associations for visuo-spatial neglect and anosognosia however the assessment of anosognosia focused only on the explicit awareness of patient's own disabilities. Berti et al. (1998) completed a case report presenting evidence that dissociations between anosognosia for hemiplegia (AHP) and unilateral neglect could be made after stroke. This research was further developed by Berti et al. (2005) by completing a cross-sectional study reporting that patients may appear to have the cognitive ability to evaluate feedback regarding their deficits, however they may not be cognisant of the meaning of this in functional activity. Experimental studies have described dissociation between explicit and implicit processing in anosognosia for motor impairment (Fotopoulou et al., 2010; Moro et al., 2011). Fotopoulou et al. (2010) completed an experimental study with 14 patients with stroke and resulting anosognosia for hemiplegia (AHP). They describe how patients with AHP claimed that they were able to hold a tray with two hands, but in the execution of this task, it transpired that the patient was in fact using only one hand, indicating explicit knowledge of hemiparesis but no implicit awareness of the condition. These results provide strong experimental support for the specific dissociation between implicit and explicit awareness of deficits. It also has significant implications on the results reported in earlier studies and adds some degree of uncertainty to prevalence results.

1.3.2 The interface between self-awareness and IADL Performance

Following stroke, individuals often demonstrate similar difficulty in the performance of instrumental activities of daily living (IADL; Goverover & Hinojosa, 2002; Neistadt, 1993). IADL are considered to be of a higher order than BADL, as they involve the operation of a tool or instrument and require more steps for successful completion than do most basic ADL, such as eating or bathing (Fitzgerald et al. 1993). Neistadt (1993) showed a significant correlation between constructional skill deficits and meal preparation (considered an IADL) in people with TBI. IADL assessments have been used as evaluations of everyday performance across a broad range of complex activities considered essential for independent living. Goverover and Hinojosa (2002) showed a relationship between executive ability and everyday competence using an assessment that included three IADL domains, taking medications, using the phone, and managing finance. Goverover (2004) further developed this by examining the association between executive function, self-awareness and IADL performance in individuals with TBI. They reported strong correlations between self-awareness and IADL performance and indicated that higher order cognitive skills such as categorisation and deductive reasoning abilities were essential for appropriate IADL performance.

1.3.3 The interface between self-awareness and cognitive performance

Cognitive impairment is a major cause of disability after stroke (Pater et al., 2003) with subtle cognitive deficits influencing participation and quality of life during stroke recovery (Duits et al., 2008). Boosman et al. (2014) completed an exploratory study

addressing sub-acute and chronic stroke patients' self-awareness of memory functioning. The results indicated that impaired awareness of memory functioning was observed in patients who had good overall functional outcome as well as individuals with higher dependency requirements. This study reported that 50% of patients over-estimated or under-estimated their memory functioning. Cumming et al. (2013) notes that, stroke tends to have greater impact on the cognitive skills of attention and executive function rather than on memory. Researchers have linked impaired self-awareness with lesions in the frontal lobes and resultant attentional deficits along with difficulties with self-regulation and self-monitoring (Stuss et al., 2004).

Lack of awareness of cognitive deficits is common after acquired brain injury (ABI) (Hartman-Maeir et al., 2003); a pattern that previous studies have indicated has a negative effect on occupational performance and the outcome of rehabilitation (Jehkonen et al., 2006). Lack of awareness of disability after ABI has been found to influence a person's motivation to engage in rehabilitation. It is well documented in the literature that rehabilitation plays an important role in the functional recovery of stroke patients with therapists endeavouring to restore the person's skills in functional performance and increase independence in activities of daily living (Gustafsson et al, 2012). However, it has been well described in the literature that addressing functional impairment when anosognosia is present is futile until a level of awareness is developed. Hartman-Maeir et al. (2003) reported on the awareness of deficit profile of 60 patients in a stroke rehabilitation setting. The study investigated unawareness of disabilities as defined by the discrepancy between therapist and patients rating on

ADL outcome measures. This clinical trial focused on understanding the phenomena of unawareness of disabilities after stroke and its relationship to functional recovery in stroke rehabilitation. They described the occurrence of unawareness for motor and sensory deficits as low; however, unawareness of cognitive deficits was much higher in this population. They reported the frequency of unawareness of disabilities after stroke was 73.3% at admission and 42.1% at time of discharge from a stroke rehabilitation setting. In another study, Hartman-Maeir et al. (2002) reported on the same population grouping that 30% of the entire sample (60 patients) did not spontaneously acknowledge having a stroke after questioned on reason for hospitalisation with a further 12% of patients insisting they did not have a stroke. They established that the central focus of unawareness at the rehabilitation stage of treatment was in relation to cognitive impairment.

1.4 Assessment of self-awareness in the acute setting

The lack of conceptual clarity and methodological consistency in the research to date is reflected in the diversity of methods used to assess unawareness. Research indicates that self-awareness should be evaluated before initiating an intervention programme; however, there is no consensus on a universal assessment method of this concept (Sherer et al, 1998; Gillen, 2009). Based on the assessment methods used, recent research into self-awareness has focused primarily on verbal i.e. explicit forms of awareness. However, implicit forms of self-awareness have also attracted growing interest especially during the past decade. Explicit verbal awareness has been evaluated using various questionnaires addressed to the patient about their deficits, and the information collected has been compared to different sources of information about the patient's condition dependent on the assessment procedure used, for example

medical records, neuropsychological performance, or clinician's evaluation (Berti et al, 1996). Simmond and Fleming (2003) advised that a comprehensive assessment of awareness should include an assessment of intellectual awareness, followed by a self-rated assessment of performance by the patient. Following this, a functional assessment should be completed, allowing flexibility to challenge patients. There is an exhaustive list of available tools designed to measure self-awareness, however concerns also exist regarding validity of these assessment tools in the specific context of stroke, as they were mainly utilised in a traumatic brain injury rehabilitation setting (Al Banna et al. 2015).

1.5 Rehabilitation Models

The society for Cognitive Rehabilitation in the United Kingdom have stated that awareness is the key to successful rehabilitation (Malia et al., 2004) and it is well established that unawareness poses a problem in acute and sub-acute rehabilitation (Fotopoulou et al., 2010). To date, only one systematic review has examined the clinical application of self-awareness to enhance treatment outcome exclusively in stroke (Leung and Liu 2011). This review indicated that there is no consensus on the most suitable tool for assessing self-awareness, resulting in no uniform treatment approach to address awareness deficits. Another review examined the concept of metacognition including utilisation of self-regulation, self-monitoring and compensatory strategies in relation to stroke care, assessment and management (Al Banna et al., 2015). This review highlighted that the majority of studies in relation to self-awareness skills focus on traumatic and other ABI in comparison to stroke. Of the 34 studies included, only twelve studies were found to address awareness function exclusively in patients with stroke, with only one of these studies (Skidmore et al,

2011) addressing self-awareness in the acute phase of stroke. It also highlighted that most studies examined components of awareness, mainly intellectual awareness, however did not address higher levels of anticipatory awareness including self-regulation and monitoring. Metacognition received the most attention, however when metacognition was examined in the stroke population they did not assess patients in the acute phase of illness. The review identified that few studies examined stroke populations exclusively, with a noted scarcity of quantitative research on the subject. Stroke rehabilitation continues to focus primarily on physical and cognitive deficits (attention and memory) (Al Banna et al., 2015). Despite the difficulty in measuring self-awareness, it is essential to assess metacognition and anticipatory awareness of patients and increased focus is required from the clinical perspective (Hart and Evans, 2006).

It is important to recognise that patients with impaired self-awareness may not be responsive to traditional therapy, since they fail to appreciate the necessity for rehabilitation, nor are they able to set realistic rehabilitation goals (Bar-Haim Erez et al., 2009). Schmidt et al. (2011) completed a systematic review to determine the effectiveness of self-awareness interventions that involve a component of feedback for adults with brain injury. The review suggested that feedback interventions in rehabilitation are associated with enhanced self-awareness of deficits. The study focused on 12 trials of varied methodological quality, of which three were randomised controlled trials and found moderate but statistically significant summary effect sizes in favour of a feedback intervention (standardized mean difference = 0.64 favouring feedback intervention; 95% CI 0.11–1.16, p = 0.02). Overall, the review concluded that there was evidence that feedback intervention had a beneficial impact on self-

awareness training after brain injury, with more intensive therapy improving rate of recovery in functional activities. Ownsworth et al. (2008) completed a randomised controlled trial comparing three types of interventions for self-awareness deficits. These included an individualised programme with facilitation feedback and personal goal setting; a group based education programme with peer feedback and personal goal setting; and a combined individual and group based intervention group. This study found that a combined individual and group-based programme appeared to contribute to gains focused on performance in goal-specific areas. The findings support the efficacy of awareness interventions however they are required to be goal-specific. No studies to date have directly explored differing levels of awareness and the relationship of awareness level to cognitive or functional performance in the acute stroke population.

1.5.1 Interventions for Unawareness

Ownsworth et al. (2006) completed a systematic review with a total of twelve studies which examined the empirical evidence on the awareness of deficits and rehabilitation outcome among clients with ABI. The reviewers reported that there was a trend towards an association between greater awareness of deficits and favourable rehabilitation outcomes. Liu et al. (2002) completed a case report, which indicated that self-awareness could promote performance of daily tasks, as well as relearning, and generalisation of these relearned skills for people after stroke. A longitudinal prospective study by Ekstam et al. (2007) further corroborated the findings that the increased awareness of disability was positively related to the functional performance of individuals within 12 months of stroke. This evidence supports the effectiveness

of meta-cognitive strategy training for individuals with chronic stroke, however there is limited research examining this approach in the acute phase of recovery. Skidmore et al. (2011) completed a case report reviewing the feasibility of meta-cognitive strategy training during acute inpatient rehabilitation. The report describes strategy training with a 31-year-old male who sustained a mild to moderately severe embolic stroke. Whilst this is considered a low level of evidence, the results of this are encouraging and reports positively on the use of such strategies in acute stroke. Liu et al. (2014) completed a pilot RCT with 44 participants with acute stroke to test the efficacy of self-awareness training for improving motor and cognitive functions as well as promoting task performance. The group receiving self-awareness training demonstrated significant improvements versus the control group. Both studies demonstrate the effectiveness of meta-cognitive strategy training; however, no known RCT has assessed the effects of hierarchical 'on-line' awareness training. Evidence demonstrates that self-awareness plays a vital role in rehabilitation for clients with stroke and other brain injuries but also alerts clinicians to the need to assess and intervene in self-awareness during the acute stage of rehabilitation to enable better rehabilitation outcomes.

1.6 Conclusion

In practice, unawareness is a problem in the acute and sub-acute stages of stroke and its occurrence can considerably impede rehabilitation. Patients, who have refused treatments that improve prognosis, are unaware of their limitations and require supervision because of poor safety judgement. During the past decade a key area of focus in self-awareness research has been anosognosia for motor impairment, which is understandable in view of the fact that hemiparesis is the most easily observable

deficit. However, awareness deficits for cognitive impairment need to be explored in greater depth in order to gain a more comprehensive understanding of the syndrome of unawareness after stroke. The primary aim of this study was to examine the association between self-awareness and functional performance deficits across three domains (Basic ADL; Instrumental ADL and Cognition) in sub-acute stroke. A greater understanding of the relationship between self-awareness and cognitive and functional performance in sub-acute stroke is necessary to enhance clinical decision-making concerning the need for awareness assessment and interventions and the possibility of tailoring therapeutic approaches according to individual circumstances.

CHAPTER 2 METHODOLOGY

2.1 Aim and Objectives

The primary aim of this research was to examine the association between self-awareness and functional performance deficits across three domains (Basic ADL; Instrumental ADL and Cognition) in sub-acute stroke.

The objectives were:

1) To identify patients' self-awareness of stroke-deficit within three months of stroke.
2) To investigate the association between functional outcomes of ADL performance and self-awareness

2.1.2 Hypotheses

HA - Levels of self-awareness are associated with functional performance; thus, good awareness of deficit positively influences participation in everyday activities.

Hõ- Levels of self-awareness are not associated with functional performance; thus, good awareness of deficit has no influence on participation in everyday activities.

2.2 Study Design

This is a cross-sectional observational study investigating the unawareness of deficit profile of first-event stroke patients and the impact of implicit and explicit awareness on functional performance in the acute phase of illness. The study design was developed using the Strengthening the Reporting of Observational Studies in

Epidemiology (STROBE) statement guidelines to ensure methodological validity (von Elm et al., 2007).

2.2.1 Sample Selection

Consecutive patients with a diagnosis of stroke were recruited from inpatients in Beaumont hospital, incorporating St Joseph's hospital Raheny. Recruitment took place over a 6-month period between October 2015 and March 2016. Medical teams received written and verbal notification of the study. Potential participants who met inclusion and exclusion criteria were approached by their treating occupational therapist (the gatekeeper) and invited to enrol in the study. The patient was provided with an information leaflet describing the purpose, nature and risks of the study (Appendix 1). Potential participants were then contacted in person by the gatekeeper within 48 hours, ensuring a sufficient cool-off period, and invited to participate in the study.

2.2.2 Inclusion and Exclusion Criteria

To be eligible for the study participants must have had a confirmed diagnosis of a first-event stroke. The following inclusion and exclusion criteria applied.

Inclusion criteria:

1) Clinical diagnosis of first time Stroke (Time-period: within 3 months of acute-stroke)
2) Able to provide written informed consent (MoCA scoring of 17/30 or above)

3) Deemed medically appropriate to participate in therapy by medical team
4) Residual cognitive or functional deficit post stroke based on MoCA and / or Modified Barthel screening tools
5) Able to lift a kettle and carry a cup

Exclusion criteria:

1) Medical team had deemed not appropriate to participate in active therapy
2) Patients who were unable to provide written consent to study participation
3) Severe communication problems and/or inability to comply with simple instructions
4) Post-Stroke Delirium or evidence of disorientation

2.2.3 Sample Size

The sample size was calculated using Ronan Conroy's sample size guide – long version (Conroy, 2009). Based on this guide, a sample of 30 patients provided the study with approximately a 90% power to detect a correlation of over 0.55. Less than 0.45 was unlikely to have clinical significance when investigating relationships between variables of clinical interest. Based on this sample size calculation, 30 participants were required. Therefore, a sample size of 30 participants was deemed appropriate.

2.3 Ethical Considerations

An application for ethical approval was sought and granted by the Beaumont Hospital Ethics committee and Royal College of Surgeons in Ireland Ethical committee (REC) (Appendix 2A and 2B). A pilot study was completed (Section 2.4.2) with three participants with an amendment application following this which was subsequently granted by the aforementioned ethical committees (Appendix 3A and 3B). The data collected were stored under the Data Protection Act (2003) and the Data Guidance on Research in Health Sector (2007). Each participant was given a unique code in order to uphold patient confidentiality. This was then the only identifiable marker on all record sheets and electronic records. The principal investigator (PI) had access to a separate Excel file, which linked the codes to the participants. Electronic records were stored on a password protected computer in St. Josephs Day Hospital, Raheny. Paper records were stored in a locked cabinet in St. Josephs Day Hospital. Data will be stored securely for five years. All participants participated voluntarily and provided written informed consent (Appendix 4) following screening for inclusion and exclusion criteria and receipt of a participant information leaflet. Participants were made aware of their ethical right to withdraw from the study without giving reason or personal consequences. All outcome measures focus on functional and cognitive screening and assessment. Assessment of these domains form part of routine occupational therapy assessment. There were no ethical considerations relating to the use of these outcome measures.

2.4 Assessment Procedure

2.4.1 Informed Consent

The selection criterion was applied to all patients admitted to Beaumont hospital with a confirmed stroke. Eligible participants were invited to enrol in the study by their treating occupational therapist and provided with a participant information leaflet (Appendix 1) detailing the purpose, nature and risks of the study. All participants were required to participate voluntarily and provide written informed consent (Appendix 4). The patient was given a 48-hour period to allow comprehension of the information given. Once informed written consent was received, data collection commenced.

2.4.2 Pilot study

A pilot study was completed to identify appropriate assessment procedures, risks or confidentiality issues. Three patients were recruited and assessed by the PI. Changes to the ethics application included the addition of a further outcome measure (The Kettle Test – Appendix 5). The outcome measures originally approved did not assess self-awareness beyond personal activities of daily living, thus not truly examining the relationship and influence of self-awareness on functional performance of everyday activities. The addition of this outcome measure enabled the assessment of a broad range of cognitive skills within a functional context. Timing of the assessments took approximately 45 minutes.

2.4.3 Assessment Administration

The screening of participants for eligibility for study participation was completed by the gatekeepers (treating occupational therapist). They completed the following measures:

1) The Scandinavian Stroke Severity Scale (SSSS) (Scandinavian Stroke Study Group, 1985) (Appendix 6)
2) The Modified Barthel Index (MBI) (Shah et al, 1989) (Appendix 7)
3) The Montreal Cognitive Assessment (MoCA) (Pendlebury et al., 2010) (Appendix 8)

Providing impairment had been identified in cognitive or functional performance, the patient was eligible for participation in the study. Once informed written consent was received, data collection commenced within 48 hours. Demographic and baseline information was obtained from the participant's medical chart by the PI. This information included age, gender, site of stroke lesion, and treatment of stroke, number of co-morbidities and details of living situation. All information was recorded on the data collection form (Appendix 9). This was followed by administration of three clinical measures by the PI:

4) The Frontal Assessment Battery (FAB) (Kopp et al., 2013) (Appendix 10)
5) The Kettle Test (KT) (Hartman-Maeir et al., 2009) (Appendix 5)
6) The Self-Regulation Skills Interview (SRSI) (Ownsworth et al., 2000) (Appendix 11)

Instructions were read aloud prior to each test. The assessment procedure by the PI took approximately 45 minutes to complete.

2.5 Clinical Evaluations

2.5.1 The Scandinavian Stroke Severity Scale (SSSS)

The SSSS is a 9-item scale consisting of both a prognostic score and a long-term score. The prognostic score includes measures of consciousness, gaze palsy, and limb weakness. It is designed to stratify patients into several groups, depending on their prognosis for survival. The long-term score is meant for repeated evaluations of the patient during follow-up. The long-term score does not include consciousness or gaze palsy but does include limb strength, aphasia, facial palsy, orientation, and gait. Limb strength is rated only on the symptomatic side. The SSSS has been shown to have high inter-rater and intra-rater reliability (Lindstrom et al., 1991) and has been clinically validated in several stroke studies (Scandinavian Stroke Study Group, 1985; Scandinavian stroke Study Group, 1987; Lindstrom et al., 1991). The score is calculated during the bedside neurological exam, with a score of 48 indicating normal performance on the long-term exam. It takes approximately 5 minutes to administer. Acute stroke patients with scores of 40 or greater on the SSSS long-term have a high likelihood of spontaneous recovery. The SSSS is well validated and is in widespread use in several European stroke studies (Clark et al., 1997).

2.5.2 The Modified Barthel Index (MBI)

The MBI is a 10-item scale assessing overall functional abilities in 10 activities of daily living (ADL), scoring 0 – 100 with 5-point increments (Mahoney and Barthel, 1965) (Appendix 7). It has high inter-rater and intra-rater reliability (Wells et al., 2003). It is proven to be a valid measure of ADLs and is reliable, however floor and

ceiling effects have been demonstrated at extremes of disability (Schepers et al., 2006). Despite the test's limitations, it has been used in several multicentre stroke trials and is recommended for use in the stroke population (Quinn et al., 2011).

2.5.3 Montreal Cognitive Examination (MoCA)

The Montreal Cognitive Assessment (MoCA), a screening tool developed by Nasreddine et al. (2005) is a brief 30-point global cognitive screening tool, which assesses eight cognitive domains: attention and concentration, executive functions, memory, language, visuo-constructional skills, conceptual thinking, calculations and orientation (Appendix 8). According to Nasreddine et al. (2005) the sensitivity and specificity of the MoCA for detecting mild cognitive impairment (MCI) (n=94 participants) were 90% and 87% respectively, with an excellent internal consistency (Chronbach alpha of 0.78). This test has been extensively investigated and demonstrated to be a valid and reliable measure of cognitive functioning in the stroke population (Toglia et al., 2011; Pendlebury et al., 2010; Dong et al., 2010). It has been recommended by the Canadian Stroke Consortium as the primary screening instrument for cognitive impairment in stroke since 2006 (Pendlebury et al., 2010).

2.6 Outcome Measures

2.6.1 The Frontal Assessment Battery

The Frontal Assessment Battery (FAB) is a brief battery of six neuropsychological tasks designed to assess frontal lobe function (Appendix 10). It comprises of tasks

exploring cognitive and behavioural domains that are thought to be under the control of the frontal lobes, most notably conceptualization and abstract reasoning, lexical verbal fluency and mental flexibility, motor programming and executive control of action, self-regulation and resistance to interference, inhibitory control, and environmental autonomy (Dubois et al., 2000). Dubois et al. (2000) reported good psychometric properties with inter-rater reliability (kappa – 0.87, $p < 0.001$), internal consistency (chronbach's coefficient alpha = 0.78), and discriminant validity (89.1% of cases correctly identified in a discriminant analysis of patients and controls). Kopp et al. (2013) reported good sensitivity of performance on the FAB to frontal lobe damage in right-hemisphere-damaged first-ever stroke patients.

2.6.2 The Kettle Test

The Kettle Test is a brief performance based assessment of domestic activities of daily living. It assesses a broad range of cognitive skills within a functional context. The Kettle Test uses the functional tasks of preparing a hot beverage, thus assessing the cognitive – functional and problem-solving skills of patients. Hartman-Maeir et al. (2009) examined the inter-rater reliability of the Kettle Test between four occupational therapists across two sites. This test demonstrates high inter-rater reliability (Spearman correlation coefficient = 0.85 and 0.92) in a study of ABI patients across two sites. These authors also examined the convergent validity of the Kettle Test by comparing it to other commonly used measures of cognitive-functional ability in 36 stroke patients and 36 healthy controls. Excellent correlations were found between the Kettle Test and the cognitive scale of the functional independence measure using Pearson Correlation Coefficients (r = -0.659). The test targets cognitive abilities in a

functional context and the test was found to moderately correlate with conventional cognitive measures such as the Mini-Mental State Examination and the Clock Drawing Test (all significant at $p < 0.01$). Performance of participants after stroke was not related to their motor status or educational background with no significant difference found ($p > 0.01$). The results of this study suggest that performance on the Kettle Test is representative of the functional outcome of patients who are discharged to home. This test takes between 5 – 15 minutes to administer.

2.6.3 Self-Regulation Skills Interview (SRSI)

The Self-Regulation Skills Interview (SRSI) is a semi-structured interview designed to measure a range of metacognitive skills including self-regulation skills by focusing on a main area of difficulty experienced by the person with ADL's (Ownsworth et al., 2002) (Appendix 11). Ownsworth et al. (2000) reported good internal consistency, test-retest reliability and inter-rater reliability. The clinical tool reveals three factors including awareness, readiness to change and strategy behaviour. The concurrent validity of the scale has been well validated in the ABI population, with a well-established value for use in post-acute assessment and is the only validated measure assessing self-awareness and self-regulation (Al Banna et al., 2015). Based on the responses to the Self-Regulation Skills Interview (SRSI), participants were classified as having Very High, Moderate or Very Low levels of self-awareness. Each question was scored using a 10-point Likert scale based on guidelines from the author of the outcome measure (Ownsworth, et al., 2000). The scores reflect level of awareness, self-rating of readiness to change, and strategy behaviour (level of skills: 0 [very high],

5[moderate], 10[very low]). The following categories were determined for the purposes of analysis.

- Very High Awareness: [Scores of 0 – 16]; Overall the person describes clearly and comprehensively how they are aware of their difficulties. They may appear sensitive to slight changes and indicate their awareness of different aspects using specific examples. They provide a large number of strategies from various approaches, they use examples to demonstrate and not how people have commented and that aspects of their lives have changed as a result of using the strategies

- Moderate Awareness: [Scores of 17 – 33]; Overall the person describes a number of ways or signs which tell them that they have difficulties. The signs may be internal (e.g thoughts), their own behaviour or external (e.g comments or expressions from people). They describe a small number of examples of strategies they are using however they are vague ideas and are unable to provide a reliable explanation of circumstances.

- Very Low Awareness: [Scores of 34 – 50]; Overall the person is unable to describe how they know that they experience the problem or what they notice despite prompts and having the question clarified. The person states that they have no idea or that there are no strategies despite prompting and clarification of what a strategy means. They state that they haven't been using any strategies or that their difficulties have increased.

2.7 Statistical Analysis

Statistical Package for the Social Sciences (SPSS) for statistical analysis version 21.0 was used to analyse the data. Descriptive statistics including mean and standard deviation were derived for continuous variables including participant characteristics and median and interquartile range (IQR) for non-parametric data. These were presented using graphs and tables (scatter-plots and pie-chart). Data were examined for normality using skewness and kurtosis, normal probability plots (normal Q-Q plots) and the Shapiro-Wilk Statistic (as sample size less than 50) and histograms. For parametric data, means and SD were calculated. For non-parametric data, median, IQR and minimum-maximum ranges were reported.

The correlation between self-awareness and the measures for physical function and cognitive function were calculated using a Spearman rank-order correlation co-efficient test for non-parametric data. Cohen's (1988) guidelines on interpretation of the r value were used to examine the strength of the relationship (Table 2.1). The percentage variance was calculated by squaring the r value and multiplying this by 100. Data were examined to determine if self-awareness impacts on functional outcome, with a significance value of $P<0.15$ (McCowan et al., 2011). The significance of correlation in the functional assessments and the SRSI and cognitive screens were calculated using a linear regression analysis. Linear regression analysis was performed on the MBI and the KT to determine if self-awareness influences functional performance. Additionally patients were divided into a high and low-moderate level of self-awareness. The groups were then compared using the Mann-

Whitney-U test for non-normally distributed data for comparison. The results are presented in chapter three.

Table 2.1 Strength of Correlational Value

Strength of Correlational Value	
r-value	**Strength of Correlation**
0.1-0.29	Low strength of Correlation
0.3-0.49	Medium strength of Correlation
0.5-1.0	Large strength of Correlation

r=Spearman's rank correlation coefficient; Cohen's (1988) guidelines on interpretation of coefficient

CHAPTER 3 RESULTS

3.1 Introduction

The primary aim of this research was to examine the association between self-awareness and functional performance deficits across 3 domains (Basic ADL; Instrumental ADL; Cognition) in sub-acute stroke.

The objectives were:

1) To identify patients' self-awareness of stroke-deficit within three months of stroke.
2) To investigate the association between functional outcomes of ADL performance and self-awareness.

3.2 Participant Flow

Recruitment took place from December 2015 to March 2016. Seventy-four patients with confirmed stroke were admitted to Beaumont Hospital within this time-frame and screened for inclusion in the study. Thirty-four were eligible for inclusion in the study with twenty-three consenting to participate. The final study sample was nineteen. The flow of patients in the study is outlined in Figure 3.1.

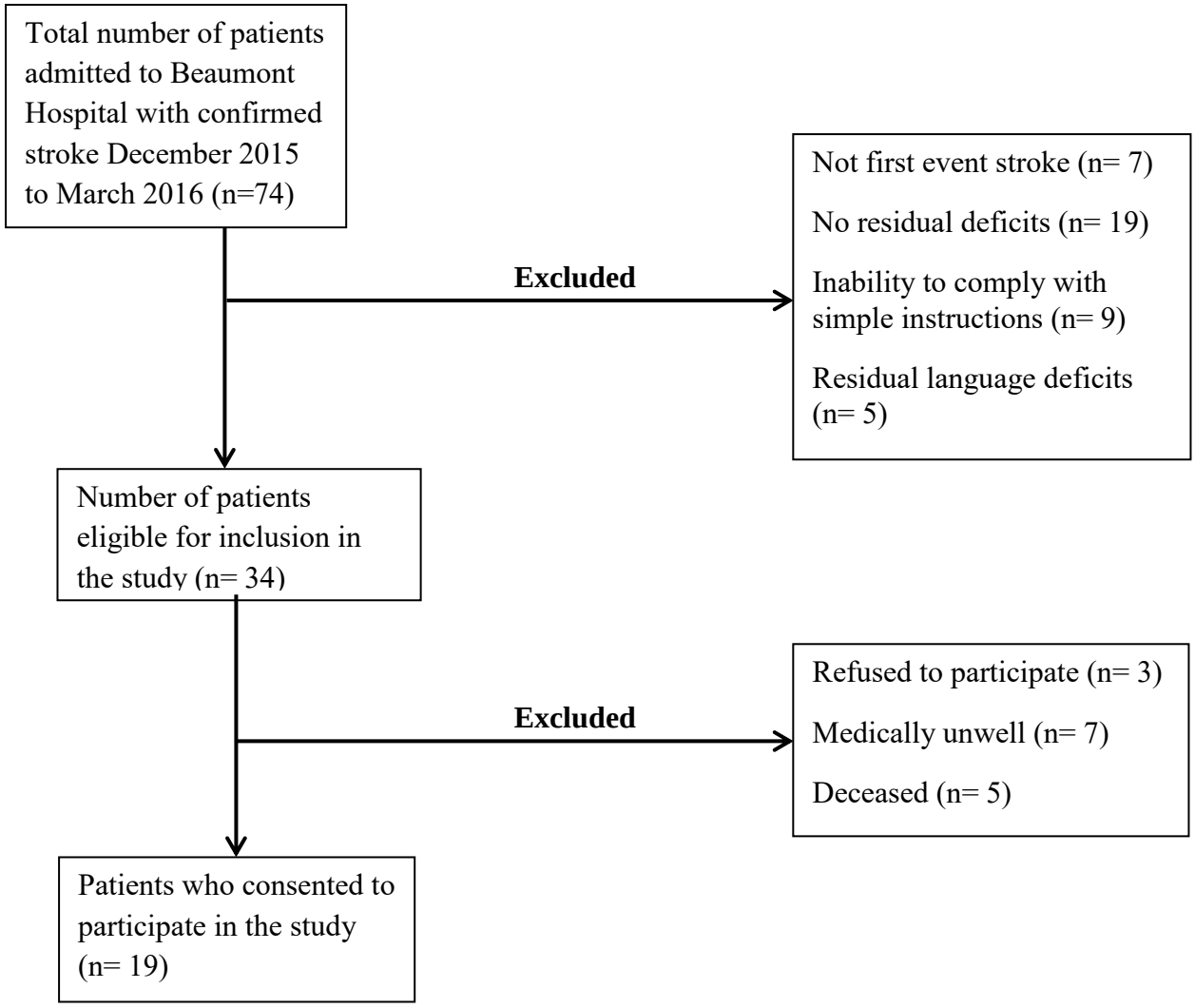


Figure 3.1 Participant Flow through the Study

3.3 Demographic Details and Clinical Profile

3.3.1 All Participants

Demographic details of the participants are displayed in Table 3.1. Nineteen adults with stroke participated in the study with the median (IQR) age of 73 (18) years. The majority of the participants were female 57.9% (n=11) and presented with a right hemispheric lesion (63.2%). The majority of participants had a stroke of ischaemic

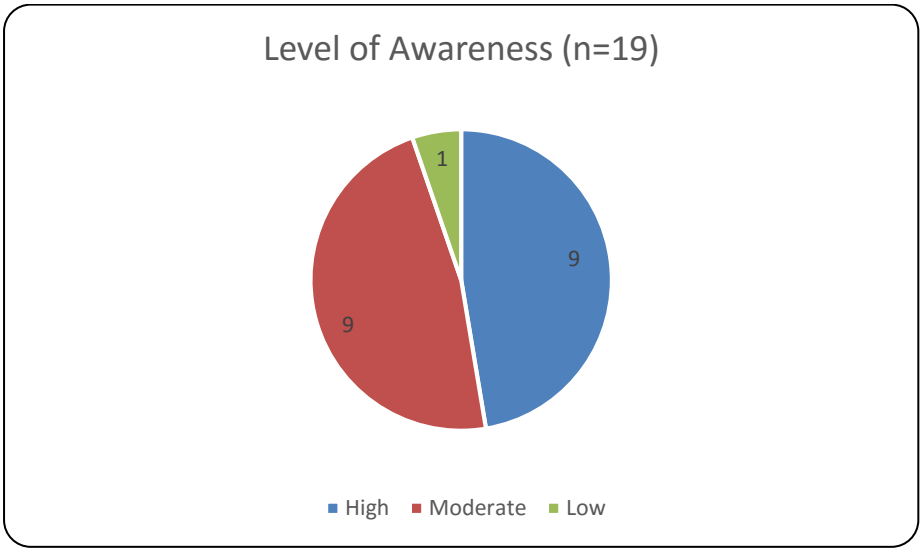
origin (64.4%) and were classified on the Scandinavian stroke severity scale, with 73.6% (n=14) scoring within the mild range. The mean (±SD) length of time since stroke was 4.8 (±2.8) weeks and the median (IQR) number of comorbidities of the sample was 2 (3). Participants required a mean (±SD) of 6 (±3.3) medications and less than half of the sample lived alone (31.6%, n=6). The median (IQR) Modified Barthel Index score of 90 (50) indicated a mild - moderate level of functional dependency. The mean cognitive performance scoring on the MoCA screen was 22.68 (±3.14) indicating the majority of participants were classified as having a mild degree of cognitive impairment. Baseline data are presented in Table 3.1. Based on the responses to the Self-Regulation Skills Interview (SRSI), participants were classified as having Very High (n=9), Moderate (n=9) or Very Low (n=1) levels of self-awareness. These are graphically represented in Figure 3.2. This indicates that almost half (47%) of the participants in this study demonstrated high awareness with the remaining participants (53%) demonstrating low-moderate awareness. Comparison of sub-groups is further analysed later in the results chapter.

Table 3.1 Demographic Details and Clinical Profile (n=19)

Demographic & Clinical Profile					
		Range	**n (%)**	**Mean (±SD)**	**Median (IQR)**
Age		19 - 92		69.8 (±16.7)	73 (18)
Gender	Female Male		11 (57.9%) 8 (42.1%)	N/A	N/A
Lesion Site	Right Left		12 (63.2%) 7 (36.8%)	N/A	N/A
Type of Stroke	Ischaemic Haemorrhagic		13 (64.4%) 6 (35.6%)	N/A	N/A
SSSS	Mild Moderate Severe		14 (73.6%) 3 (15.7%) 2 (10.7%)	N/A	N/A
Number of co-morbidities		0 - 7		3.1 (±3.3)	2 (3)
Time since stroke (weeks)		1 - 11		4.8 (±2.8)	4 (6)
Number of medications		2 - 12		6.05 (±3.3)	5 (5)
MoCA		17 - 28		22.7 (±3.1)	23 (5)
MBI		10 - 100		73.7 (±28.6)	90 (50)

n = number of participants; % = percentage; SD = Standard Deviation; IQR = Interquartile Range; SSSS = Scandinavian Stroke Severity Scale; MoCA = Montreal Cognitive Assessment; MBI = Modified Barthel Index

Figure 3.2 Levels of Self-Awareness



Scoring on SRSI: High (0-16); Moderate (17 – 33); Low (34 – 50)

3.4 Results of Outcome Measures

A summary of the results of each outcome measure can be seen in Table 3.2. The results of the normality tests indicated that the MoCA, FAB and SRSI data were normally distributed and were therefore treated as parametric data for correlational analysis. The data recorded on all other outcome measures (MBI and KT) were not normally distributed ($p<0.05$), therefore medians, minimum, maximum and IQR were reported for these measures due to the non-parametric nature of the data. The mean (±SD) score on the SRSI was 16.53 (±8.82) with a total range of 4 – 39, indicating the average score on the awareness scale was moderate self-awareness. The mean (±SD) score on the FAB was 14.26 (±2.4), indicating the majority of participants scored within normal range of executive skill function. Other baseline variables such as age, number of co-morbidities, stroke severity and number of medications and time since stroke were also assessed for normality, with only the latter two variables being normally distributed.

Table 3.2 Clinical Profile on Assessment and Normality of the Data (n=19)

Outcome Measures	Range	Median (IQR)	p-value
Functional Dependence			
MBI	10 - 100	90 (50)	p = 0.003
KT	0 - 33	8 (7)	p = 0.000
Self-Awareness Measure		**Mean (±SD)**	
SRSI	4 - 39	16.53 (±8.82)	p = 0.261*
Cognitive Performance			
MoCA	17 - 28	22.68 (±3.14)	p = 0.769*
FAB	10 - 18	14.26 (±2.49)	p = 0.434*

* Normal distribution statistical significance $p \geq 0.05$; IQR = Interquartile Range; SD = Standard Deviation; MBI = Modified Barthel Index; KT = Kettle Test; SRSI = Self-Regulation Skills Interview; MoCA = Montreal Cognitive Assessment; FAB = Frontal Assessment Battery.

3.5 Association between outcome measures and demographic details

The results of the correlation analysis for the association between the outcome measures and the demographic details can be seen in Table 3.3. Level of function as measured on the MBI was significantly associated with stroke severity and type of stroke ($p<0.05$). Self-awareness as measured on the SRSI was only associated with type of stroke, demonstrating low levels of association with other demographic measures. The FAB demonstrated significant correlation with age ($p=0.04$). Cognitive function as measured by the MoCA and IADL function as measured by the Kettle Test did not demonstrate any statistically significant relationship with demographic measures.

Table 3.3 Association between outcome measures and demographic details (n=19)

Association between Outcome Measures and Demographics						
Outcome Measure	**Age**	**Gender**	**SSSS**	**Time Since Stroke**	**Lesion Site (Right / Left)**	**Type of Stroke (Ischaemic / Haemorrhagic**
MBI[b]	p=0.66 r=0.11	p=0.14	p=0.00* r=0.80	p=0.51 r=-0.16	p=0.09	p=0.02*
KT[b]	p=0.16 r=0.34	p=0.72	p=0.35 r=-0.23	p=0.05 r=0.46	p=0.11	p=0.61
SRSI[b]	p=0.60 r=0.13	p=0.94	p=0.92 r=0.03	p=0.56 r=0.14	p=0.21	p=0.04*
MoCA[b]	p=0.09 r=-0.40	p=0.78	p=0.99 r=0.00	p=0.24 r=-0.28	p=0.18	p=0.10
FAB[b]	p=0.04* r=-0.49	p=0.35	p=0.10 r=-0.39	p=0.09 r=-0.40	p=0.12	p=0.10

[b]=spearman rank correlation coefficient; *statistical significance set at p-value<0.05 level (2-tailed); r=correlation coefficient; MBI = Modified Barthel Index; KT = Kettle Test; SRSI = Self-Regulation Skills Interview; MoCA = Montreal Cognitive Assessment; FAB = Frontal Assessment Battery.

3.6 Association between Self-Awareness and Functional Performance

The results of the correlation analysis for the association between self-awareness and cognitive and functional outcome measures can be seen in Table 3.4 and Figure 3.3 and 3.4. Based on the interpretation of correlation coefficients by Cohen (1988), the SRSI had a very strong inverse correlation with the MoCA (r = -0.815), indicating that high levels of cognition as measured by the MoCA indicate high levels of self-awareness. A strong positive correlation was demonstrated with the Kettle Test (r = 0.521), again indicating that effective performance on this one component of IADL indicates higher levels of self-awareness. There was no statistically significant relationship found between the SRSI and the MBI. This indicates that there is no correlation between functional performance as measured on the MBI and self-awareness. The FAB showed a trend towards statistical significance (p=0.08), however did not meet the criteria for significance.

Table 3.4 Correlation between SRSI and outcome measures

SRSI				
Outcome Measure	**Correlation Co-efficient**	**Significance (p-value)**	**Variance**	**Intensity of correlation**
MoCA[a]	- 0.815	0.000**	66.4%	Strong Negative
FAB[a]	- 0.411	0.080	8.3%	Weak Negative
MBI[b]	- 0.015	0.951	0.02%	Weak Negative
KT[b]	0.521	0.022*	27.1%	Strong Positive

SRSI = Self-Regulation Skills Interview; [a]=pearson correlation coefficient; **Correlation is significant at the 0.01 level (2-tailed); MoCA = Montreal Cognitive Assessment; FAB = Frontal Assessment Battery. [b]=spearman rank correlation coefficient; *Correlation is significant at the 0.05 level (2-tailed); MBI = Modified Barthel Index; KT = Kettle Test

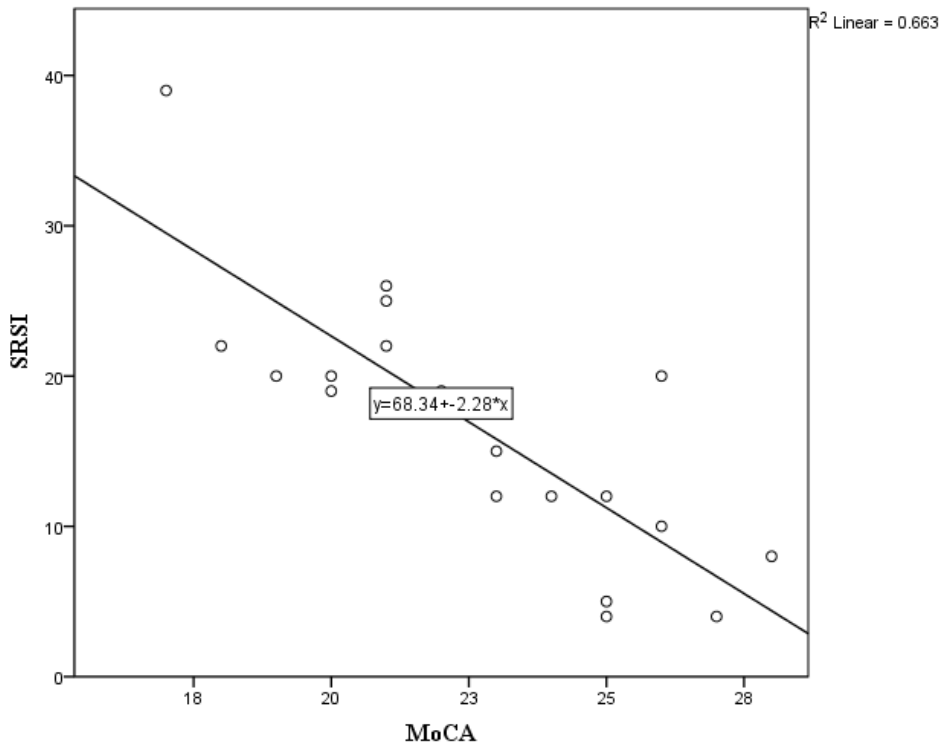


Figure 3.3 Association between SRSI and MoCA

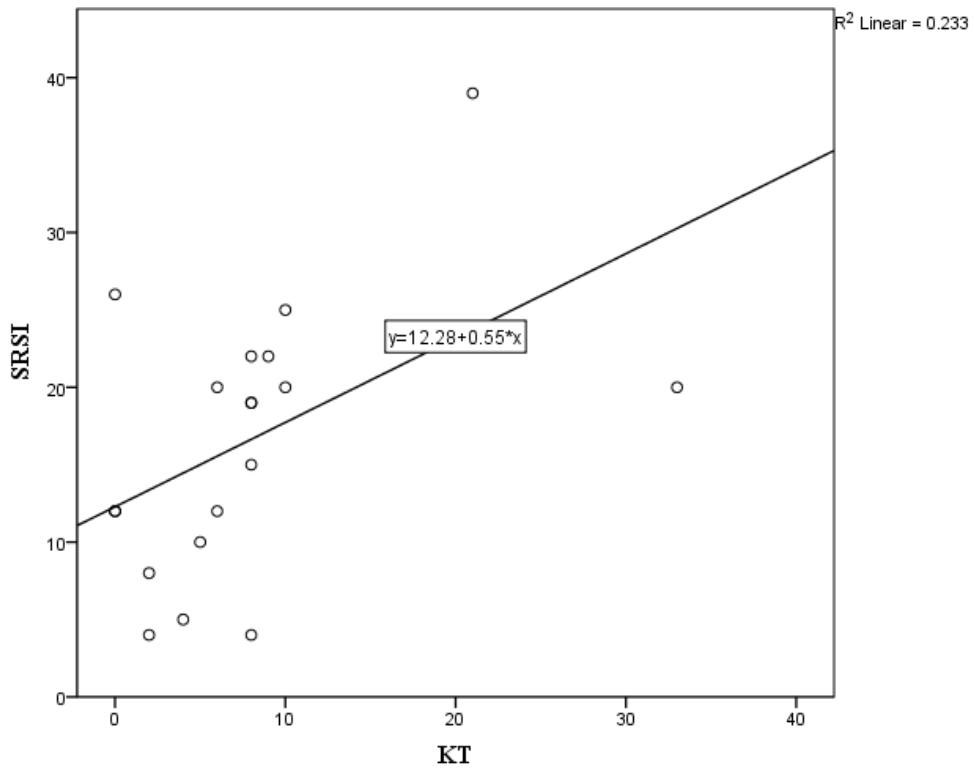


Figure 3.4 Association between SRSI and KT

3.7 Linear Regression Analysis

3.7.1 Univariate regression with the MBI as dependent Variable

The association between functional performance outcome measures and other variables was further examined using linear regression analysis (Table 3.4). In order to determine if ADL functional performance as measured by the MBI could be based on self-awareness or cognitive measures, the association between the MBI and other outcome variables was further examined using linear regression (Table 3.4). Stroke severity explained 85.4% variance on the MBI (p=0.000), with the Kettle Test explaining 29.5% variance on the MBI and was statistically significant (p=0.016). The MoCA and FAB account for very low levels of variance on the MBI, and interestingly the SRSI explained no variance on the MBI (0%). This indicates that self-awareness has no predictive value on functional performance as measured by the MBI.

Table 3.5 Results of univariable linear regression with the MBI

Dependent Variable: Modified Barthel Index				
Outcome Measure	**Significance (p-value)**	**R**	**r^2**	**%**
Age	0.179	0.322	0.103	10.3%
Gender	0.086	0.404	0.163	16.3%
SSSS	0.000*	0.924	0.854	85.4%
KT	0.016*	0.543	0.295	29.5%
MoCA	0.798	0.063	0.004	0.4%
FAB	0.660	0.108	0.012	1.2%
SRSI	0.956	0.014	0.000	0%

Significance determined at the P<0.15 level; Correlations coefficients by Cohen (1988); r=correlation coefficient, r^2 =coefficient of determination; % = percentage variance; SSSS = Scandinavian Stroke Severity Scale; KT = Kettle Test; MoCA = Montreal Cognitive Assessment; FAB = Frontal Assessment Battery; SRSI = Self-Regulation Skills Interview

3.7.2 Univariable regression with KT as dependent variable

Further univariable linear regression analysis was completed with the Kettle Test to determine if this one component of IADL performance could be based on self-awareness or cognition. Stroke severity explained 22.8% variance, however the MoCA assists in explaining 33.5% of the variance in participants' functional scores as indicated by the lowest r^2 value (Table 3.4). The self-awareness of deficit measure (SRSI) assists in explaining 23.3% of the variance in functional performance, thus awareness levels account for almost a quarter of the variance in participants' functional score on the KT. This indicates that self-awareness has a predictive value in patients' performance on the KT.

Table 3.6 Results of univariable regression with the Kettle-Test

Dependent Variable: Kettle-Test				
Outcome Measure	**Significance (p-value)**	**R**	**r^2**	**%**
Age	0.290	0.256	0.066	6.6%
Gender	0.410	0.201	0.040	4%
SSSS	0.039*	0.478	0.228	22.8%
MBI	0.016*	0.543	0.295	29.5%
MoCA	0.009*	0.579	0.335	33.5%
FAB	0.024*	0.514	0.264	26.4%
SRSI	0.036*	0.483	0.233	23.3%

Significance determined at the P<0.15 level; McCowan et al. (2011). Correlations coefficients by Cohen (1988); r=correlation coefficient, r^2 =coefficient of determination; % = percentage variance; SSSS = Scandinavian Stroke Severity Scale; MBI = Modified Barthel Index; MoCA = Montreal Cognitive Assessment; FAB = Frontal Assessment Battery; SRSI = Self-Regulation Skills Interview

3.8 Level of Self-Awareness of stroke-deficit within three months of stroke.

Based on the responses to the Self-Regulation Skills Interview (SRSI), participants were divided into two groups for comparison with other variables; high awareness (n = 9) and low-moderate awareness (n=10). There were no significant differences between the groups in age, time since stroke, stroke severity or functional performance as scored on the MBI. There were however, significant differences in other characteristics including number of co-morbidities (p=0.021) and cognitive function as measured by the MoCA (p = 0.001) and IADL performance as measured on the Kettle Test (p = 0.008). Comparison of characteristics for the groups are presented in Table 3.7.

Table 3.7 Comparison of Clinical Characteristics

High versus Low-Moderate Levels of Self-Awareness					
Variables	**High Awareness (n=9)**		**Low-Moderate Awareness (n=10)**		**p-value**
	N (%)		**N (%)**		
Gender: Female	5 (26.3%)		6 (31.6%)		0.845
Lesion Site: Right	2 (10.5%)		5 (26.3%)		0.210
Type of Stroke: Infarct	5 (26.3%)		8 (41.2%)		0.252
	Mean(±SD)	**Median(IQR)**	**Mean(±SD)**	**Median(IQR)**	
Age	70.4 (13.9)	70(18)	69.3 (19.7)	69(19)	0.842
No. of Medications	5.2 (3.5)	4(6)	6.7 (3.2)	6.5(4)	0.779
No. of Co-Morbidities	2.9 (1.5)	2(3)	3.2 (2.5)	2(5)	0.021*
Week(s) since stroke	5(3.9)	2(7)	4.7(1.7)	4(3)	0.661
MBI	80.6 (22.9)	95(35)	67.5 (32.8)	85(58)	0.315
KT	3.9 (3.1)	4 (6)	11.3 (9.2)	8.5 (5)	0.008*
MoCA	25.1 (1.69)	25 (3)	20.5 (2.46)	20.5 (3)	0.001*
FAB	15.1 (2.3)	15 (4)	13.5 (2.5)	13.5 (4)	0.182
SRSI	9.1 (4.1)	10 (8)	23.2 (6.1)	21 (6)	0.000*

Mann-whitney-U Test of Significance; IQR = Interquartile Range; n = number of participants; % = percentage; SD = Standard Deviation; SSSS = Scandinavian Stroke Severity Scale; MoCA = Montreal Cognitive Assessment; MBI = Modified Barthel Index; *statistical significance set at p-value<0.05 level.

3.9 Summary of Results

The primary aim of this research was to examine the association between self-awareness of stroke impairment and functional performance across domains of BADL, IADL and cognitive performance in the sub-acute stroke population. These results demonstrated statistically significant high associations between self-awareness and cognitive performance as measured by the MoCA and one component of IADL functional performance as measured by the Kettle Test. There was no statistically significant relationship found between the SRSI and the MBI indicating self-awareness has no relationship with functional independence as measured on the MBI. Data were further analysed to determine if self-awareness and cognition impact on functional performance by completing univariable linear regression with functional outcome measures. The SRSI explained no variance on the MBI (0%), however explained 23.3% variance on the Kettle Test. There were strong correlations observed between the Kettle-Test and the MoCA, FAB and SRSI measures. Thus, increasing levels of self-awareness and cognition are associated with increasing performance on the Kettle Test. Sub-groups analysis and comparison by participant's level of awareness (high versus low-moderate awareness), the only significant differences between the groups were scores on MoCA and KT screening tools. These results will be discussed in Chapter 4.

CHAPTER 4 DISCUSSION

4.1 Introduction

The results of this study have demonstrated statistically significant high associations between self-awareness of stroke impairment and components of functional performance of ADL's in the sub-acute stroke population. This supports the use of a self-awareness tool as part of a multifactorial assessment of stroke impairment. However, the sample size (n=19) did not meet the required sample size (n=30), which does place uncertainty on the clinical significance of the relationships found between variables. Results will be discussed further to explore the correlations between functional ADL performance and the self-awareness measure (SRSI) and the relationship between cognitive performance and the SRSI. The explained variance between each of these outcome measures will also be explored.

4.2 Demographic Review

The study aimed to include a broad spectrum of stroke patients with varying degree of stroke deficit. However, the study design necessitated implementation of certain inclusion and exclusion criteria including patients needed to have a diagnosis of a first event stroke with residual functional or cognitive deficits (MoCA >17/30) and no residual language deficits. This resulted in a large number of patients excluded from the study and the majority of participants being within the mild range of stroke severity (n=14). The mild stroke population has been found to represent nearly half of the population seen in the acute care stroke setting (Wolf et al. 2009). Patients who present with mild stroke symptoms may have subtle stroke deficits, with research

indicating that executive dysfunction is present in 30-60% of the mild stroke population (Wolf et al. 2010). However, the majority of these patients are discharged home without a referral to rehabilitation services (Wolf et al, 2013). This may account for the large number of patients in this study excluded due to 'no residual deficits' found on initial stroke assessment. The clinical profile of this sample demonstrated a similar trend for gender, stroke severity and time since stroke to previously published data for awareness deficits (Barrett et al. 2014; Boosman et al. 2014), however the population of both comparable studies were community dwelling, and therefore results should be interpreted with caution.

4.3 Stroke Awareness

4.3.1 Levels of Awareness

The majority of participants (53%) demonstrated a low-moderate level of self-awareness of stroke deficits as measured by the SRSI. These results are similar to findings by Boosman et al. (2014) who classified 50% of community dwelling patients with good functional outcome post stroke as having poor awareness of memory functioning in relation to medication management. The majority of patients in this study were determined to have had a 'mild' severity stroke by the SSSS and a mild level of functional dependency in line with the MBI. More than half of this population presented with only low-moderate levels of self-awareness of stroke deficit which raises important issues concerning vulnerability of patients with milder stroke symptoms and associated impaired self-awareness. It highlights the importance for healthcare professionals to carefully assess patients' understanding of their diagnosis and also of the recommendations being provided. Prigatano (2009) and Wolf et al.

(2013) highlighted concerns for patients presenting to the acute environment with mild stroke in relation to appropriate management post-acute phase of care. The majority of the literature relating to self-awareness and cognition after stroke has focused on the moderate to severe stroke population with little research relating to mild stroke as they are expected to make a complete recovery independent of rehabilitation services (Edwards et al. 2006).

4.3.2 Implications of low levels of self-awareness

With increasing pressure in our healthcare system for rapid discharge of patients, there is a risk that patients presenting with mild stroke will be overlooked for full functional and cognitive assessment. The National Stroke Guidelines (IHF, 2010) recommend all acute stroke patients have early comprehensive multidisciplinary assessment (including therapy assessment within 48 hours) of admission to an acute stroke unit. However, without early admission to stroke units and early identification of awareness deficits, individuals with mild stroke may experience poor outcomes in complex instrumental activities of daily living. The results of this study highlight the level of self-awareness in the mild stroke severity group and help justify the necessity to assess awareness and cognition immediately post-stroke in order to make accurate and appropriate rehabilitation recommendations. With levels of self-awareness of impairment demonstrated in this study, compliance of mild stroke patients may be lower than expected with post-stroke recommendations such as medication management, dietary guidelines and physical activity. This research further highlights the importance of addressing self-awareness of deficit through assessment and

intervention in the acute phase of stroke recovery. This is imperative for patients presenting with stroke of all degree of severity.

4.4 High versus low-moderate levels of self-awareness

Potential differences in post-stroke functioning and levels of awareness were examined by dichotomising the group between high and low-moderate levels of awareness. On comparison, there were no significant differences between the groups in gender, stroke severity, and time since stroke or functional independence as measured by the MBI. The only statistically significant differences between the groups were in relation to the MoCA ($p=0.001$) as a measure of cognitive functioning and the KT ($p=0.008$) as a measure of one component of IADL performance. Thus, cognitive scoring and functional performance were the only statistically significant differences between groups of differing levels of awareness. These results are in line with previous studies and with cognitive theories of awareness assessment (Boosman et al. 2014; Al Banna et al. 2015). Boosman et al. (2014) determined that impaired awareness of memory functioning can be observed in patients with stroke who have a good functional outcome, while Al Banna et al (2015) identified that metacognition (explicit awareness) is a key area to be addressed post-acute stroke. Overall this finding provides initial support for the necessity of assessing self-awareness and function beyond BADL's in mild stroke. However, caution is employed with this finding in light of sub-group analysis being completed in a small sample size.

4.5 Measures of Functional Activity

4.5.1 Functional ADL Performance in relation to the SRSI

The Modified Barthel Index is an accepted reliable measure of global ADL performance (Schepers et al., 2006). Sherer et al. (2003) studied impaired self-awareness in the TBI population, revealing that early impaired self-awareness was predicted by age and functional status as measured by the Functional Independence Measure (FIM). In contrast, the results of the correlation analysis for the association between self-awareness and functional performance in this study as measured by the MBI demonstrated no relationship of statistical significance (r=- 0.015). Quinn et al (2010) highlights that sensitivity of the MBI is poor across the range of possible outcomes, particularly in mild stroke due to floor and ceiling effects which may account for the poor correlation in this study. Gialanella et al. (2008) highlights that even mild unawareness of motor impairments could lead to poor rehabilitation and recovery with these deficits associated with overall poor stroke outcome.

The only associations determined on regression analysis with the MBI were stroke severity (85.4% variance) and the Kettle Test (29.5% variance). The MoCA and FAB accounted for very low variance on the MBI. These are similar findings to Akbari et al (2013) who concluded the MBI does not correlate with higher-order functions in the sub-acute stroke population. This is also consistent with a cross-sectional study completed by Perneczky et al. (2006) who concluded there are very small correlations between cognitive abilities and BADL's in a population of patients with mild cognitive impairment. To this author's knowledge, there are no other studies comparing the MBI with the SRSI, thus this finding highlights the importance of awareness

assessment with the mild stroke cohort. It also reinforces the importance of ADL assessment beyond BADL assessment for all stroke patients. There is a danger that patients who present with milder stroke, with good physical outcome will not be assessed beyond basic ADL's in the acute environment. IADL assessments provide therapists with an avenue for employing hypothetico-deductive reasoning to establish patients' awareness, cognitive, perceptual, psychosocial and physical functioning which are essential areas of assessment for all patients who present with stroke. The strikingly low correlation between the SRSI and the MBI highlights the requirement of completing self-awareness assessment with all stroke patients. It further builds on the research by Stucki et al. (2005) and Skidmore et al. (2011) that suggest providing metacognitive assessment and detecting self-awareness impairment to provide strategy training, may be optimal in the acute phase of recovery.

4.5.2 Functional IADL Performance in relation to the SRSI

The results of the present study indicate that performance on the Kettle Test as one component of IADL performance has strong positive association with self-awareness as measured by the SRSI (r=0.521). That is, a low level of awareness of functional status was correlated with poor performance on the KT. These results are consistent with findings in the literature relating to self-awareness correlating highly with IADL performance in the TBI population group (Goverover, 2004, Goverover et al, 2007). Goverover (2004) examined the association between executive function, self-awareness and everyday functional performance in individuals with TBI. This study utilised the Revised Observed Tasks of Daily Living (OTDL-R) measure of everyday competence that includes three IADL domains: medication use, telephone use and

financial management. In contrast this study only examined the use of one IADL task: preparing a cup of tea which may influence the generalisability of this studies result. Goverover et al (2009) also found similar high correlations between self-awareness and IADL function in an MS population. These authors suggest that self-awareness of functional status provides information to predict functional performance. Thus, better self-awareness of functional status can predict better IADL performance. Similarly, the present study provides initial evidence of strong correlations between self-awareness and IADL performance; however it is limited to one component of functioning.

Univariable linear regression analysis was completed with the Kettle Test as the dependent variable to determine if this one component of IADL performance could be based on self-awareness or cognition. The MoCA cognitive measure assisted in explaining 33.5% of the variance in participants' functional scores with stroke severity accounting for 22.8% variance. The self-awareness of deficit measure (SRSI) assisted in explaining 23.3% of the variance, thus awareness levels accounted for almost a quarter of the variance in participants' functional score on the KT. This indicates that self-awareness has a predictive value in patients' function on this occupational performance component. Ultimately people with higher levels of awareness as scored on the SRSI should demonstrate higher performance on the Kettle-Test, as demonstrated by this study.

4.5.3 Association between the Kettle Test and Cognition

Hartman-Maeir (2009) demonstrated moderate-strong correlations (r=0.50) between established measures of cognition (MMSE, Clock-drawing Test, Star Cancellation Test) and the validity of the Kettle Test. Similar correlations were found in this study between the MoCA and the KT (r=0.521). The correlations between these two tests suggest that common underlying cognitive abilities including attention, memory and praxis are also being monitored by this measure. The MoCA is a well validated measure of cognition in the stroke population; this finding provides further evidence for the use of the Kettle Test in this population group as a measure of cognitive functional performance.

4.6 Measures of Cognition

4.6.1 Cognitive Performance in relation to the SRSI

In this study, the SRSI had a very strong inverse correlation with the MoCA (r= -0.815), indicating that high levels of cognition are strongly associated with high levels of self-awareness. Hartman-Maeir et al. (2003) demonstrated that awareness for motor and sensory deficits are better than awareness for cognitive deficits. Comparison between groups in this study based on levels of self-awareness, indicated lower levels of awareness were associated with lower scores on cognitive screening (p=0.001). Wolf et al. (2013) studied performance on cognitive assessments administered in the sub-acute phase of mild stroke at 3-weeks and again at 6-months and determined that performance remains unchanged within this time-frame. This study included a battery of cognitive assessments such as the Trail Making subtest and

the California Verbal Learning Test. Wolf et al. (2013) provide evidence that indicates that levels of cognitive performance will remain unchanged in the mild stroke population group. The strong inverse correlation demonstrated between cognitive performance and the SRSI in this study highlights concern of the vulnerability of mild-stroke patients with low levels of self-awareness and cognitive deficits. Taylor-Cooke et al. (2006) states evaluating cognitive impairment as an objective primary measure might fail to detect and incorporate the impact of self-awareness deficits in mild stroke patients. The high prevalence of low-moderate self-awareness as revealed in this study provides further weight to the importance of self-awareness assessment in the acute environment for mild stroke patients. Goverover et al (2007) completed a RCT providing evidence that treatments focused on improving awareness processes in ABI could lead to better functional outcomes. Ultimately although strong associations are demonstrated, independent evaluation of awareness and cognitive components of function should be addressed in the assessment and management of stroke patients.

4.6.2 Executive Functional Performance in relation to the SRSI

Self-awareness deficit has been largely associated with injury to the right cerebral hemisphere, or frontal-limbic connections (Barrett, 2010). Stuss and Alexander (2000) provide supporting evidence that executive function plays an important role in self-awareness. However, self-awareness did not serve as a moderator between executive function and IADL performance in the present study. While the FAB demonstrated a trend towards statistical significance ($p=0.08$) for association with the SRSI, it did not meet the criteria. Hoerold et al. (2013) identified frontal lobe frontal lesion patient's demonstrated impaired metacognitive awareness and deficits in

monitoring skills. Bivona et al. (2008) completed a cross-sectional study in the TBI population and identified a significant correlation between some components of executive system and metacognitive self-awareness. The small sample size of this group may account for the weak relationship identified in this study. The FAB did demonstrate significance for univariable regression with the Kettle Test (r=0.024). Perneczky et al. (2006) and Akbari et al. (2013) demonstrated that higher order thinking operations were significantly related to IADL performance, which may account for the significant result on regression analysis between the FAB and the Kettle Test. This result provides further preliminary evidence for IADL assessment predicting higher-order cognitive functions.

4.7 Awareness Levels and Models of Awareness

The Self-Regulation Skills Interview is the only validated measure assessing self-awareness at an implicit and explicit level. Although there is no consensus on a theoretical framework to explain deficits in self-awareness, it is imperative to describe self-awareness including classification of performance (Abreu et al. 2001). Abreu et al (2001) found a relationship between level of self-awareness and complex ADL performance in persons with ABI, demonstrating statistically significant differences for all levels of self-awareness across three tasks: dressing, meal planning and money management. These findings are consistent with theories and models of self-awareness (Toglia and Kirk, 2000). Toglia and Kirk (2000) describe a model of self-awareness that includes the concept of understanding and awareness of difficulties, while also developing solutions to these difficulties. While this study did not find statistically significant associations between self-awareness and BADL's, it did find

strong correlations with the Kettle Test as one measure of IADL complex performance. The lack of statistical association with the MBI may be due to the use of this tool as a measure of BADL's. The anticipation of difficulties in activity leads to effective use of compensatory strategies (Toglia, 2009) with overall better functional performance. Thus the importance of self-awareness assessment and intervention is further highlighted by this study in relation to IADL performance and cognition.

4.8 Findings

Overall, the prevalence of low-moderate self-awareness in a predominantly mild stroke population was high. This study demonstrated high correlations between self-awareness and cognitive performance as measured by the MoCA and a component of IADL performance as measured by the Kettle Test. Weak correlations were found between self-awareness and executive skills, with no relationship identified with BADL. One of the most important issues in stroke rehabilitation is the relationship between test and task performance that may help to predict functional outcome. In order to maximise patients' participation in the rehabilitation process, self-awareness needs to be assessed and intervention provided accordingly. Self-awareness is not a predictor of functional outcome on the MBI, however it does demonstrate strong correlations and with the KT. We investigated the relationship between self-awareness and ADL's across three domains (basic and instrumental ADL and cognition). Results showed self-awareness has a high correlation with higher level functional tasks, however low correlations were found with basic activities of daily living. Although there may be barriers to evaluating patients in the acute phase of

recovery, providing self-awareness assessment, detecting impairments and providing cognitive strategy training, may be optimal in this phase of treatment, given the evidence that supports early rehabilitation intervention (Clare et al. 2013). An improved understanding of the concept of self-awareness may have implications for rehabilitation interventions that address this impairment.

The present results have clinical implications for the rehabilitation professional. Given the level of self-awareness deficit found in this sample, the clinician needs to carefully assess patients' understanding of their post-stroke changes. This assessment needs to focus on all components of functional and cognitive performance, while also addressing behavioural changes observed following a stroke. This research further highlights the importance and appropriateness of this assessment taking place during the acute and sub-acute phases of recovery from stroke. Beyond assessment, therapists have a key role in educating patients about discrepancies in their perceptions of their post-stroke abilities. Without this type of feedback, patients often formulate and maintain unrealistic expectations of their actual abilities, which may be in conflict with remediation efforts prescribed during rehabilitation (Hibbard et al, 1992). Self-awareness deficit is associated with poor stroke rehabilitation and recovery (Hart and Evans, 2006; Al Banna et al. 2015) and even mild unawareness may adversely affect stroke outcomes. Mild stroke patients have the capability and proficiency to participate in higher-level functional activity and attempt to resume complex occupations such as employment and driving. Identifying impaired awareness post stroke will result in improved access for patients to appropriate rehabilitation services and also improved patient safety. However, stroke patients with self-awareness deficits need to be routinely identified.

4.9 Study Limitations

- Few studies have explored the relationship between self-awareness and functional performance post stroke. Lack of uniformity in the approaches used to examine self-awareness deficits is a limiting factor of this study.
- Results are only based on particular performance components of ADL's as measured by the MBI and the Kettle Test. As this was a cross-sectional research study, it cannot definitively conclude that poor self-awareness results in poorer IADL functional performance. The use of these particular outcome tools is an overall limiting factor, with appropriate stroke related tools required to identify functional and cognitive performance awareness deficits.
- The target sample size was not reached in this study. The small sample size did not enable multiple regression analysis to examine the predictive nature cognitive and awareness measures have on function.

4.10 Recommendations for Future Research

- Future research needs to systematically examine the extent of the association of self-awareness and performance across all domains of function (BADL, IADL and cognition). Only one component of IADL performance was addressed by this study. Future research needs to employ a comprehensive measure that captures the full domains of functional performance across all levels of activities of daily living.
- Future research should include a larger multi-centre study in the mild stroke population to determine true levels of explicit and implicit awareness in this population cohort.
- Future research should encompass a self-awareness measure that includes a qualitative measure to truly identify participants' thinking and values, not only based on a structured interview schedule. Self-report is invaluable to identify social and emotional consequences of brain injury.
- A proportion of patients admitted to Beaumont were ineligible to enter the study due to expressive or receptive language deficits. Further research with this cohort is warranted.
- Additionally, future research should utilize self-awareness and functional measures specific to the stroke population to increase the generalisability of the findings.

CHAPTER 5 CONCLUSION

The study investigated the association between self-awareness and functional performance across 3 domains (BADL, IADL and Cognition) in a sub-acute stroke population. The prevalence of self-awareness in the mild stroke population was demonstrated with over half of this sample determined as having low-moderate self-awareness of deficit post stroke. These results suggest assessment of self-awareness deficits post stroke is a fundamental element of the assessment process, which are in line with existing research recommendations in the TBI population group. Previous research in the area of self-awareness has focused on traumatic and other acquired brain injuries as opposed to the stroke population exclusively, with the few studies completed focusing on the rehabilitation or chronic phase of stroke recovery. This study provides evidence in support of early assessment of self-awareness deficits both in the acute and subacute phase, particularly for the mild stroke population.

The outcome measurements used in this study encompass assessment of both basic and instrumental activities of daily living. The lack of association highlighted between the SRSI and the MBI indicates the importance of ADL assessment beyond basic activities of daily living. This finding has important clinical implications in the design and implementation of stroke assessment in the acute phase of recovery, particularly relating to mild stroke patients. The assessment of self-awareness of deficit with all stroke patients will ensure the appropriate identification of impairment and transitioning of patients to appropriate services. The significant correlations identified between the SRSI and the KT highlight the importance of complex ADL assessment and warrant the use of the KT with this cohort of patients. The results confirm that

cognitive performance correlates highly with self-awareness. Thus a multifactorial approach encompassing self-awareness, cognitive and functional assessment of stroke patients is vital to minimise the potential risk to stroke patients in unidentified and untreated awareness deficits.

Decreased self-awareness impedes functional recovery. Therefore, in accordance with this evidence, self-awareness should be one of the primary assessments undertaken with stroke patients. The emergence of clinically useful standard self-awareness tools for stroke will have important implications for future assessment and rehabilitative programmes, as self-awareness is a key area that needs to be addressed at the onset of any intervention with the stroke population.

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APPENDIX 1: PATIENT INFORMATION LEAFLET

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

Patient Information Leaflet

Study title: Relationship between self-awareness and cognitive and functional performance post stroke: A cross-sectional study.

Principal Investigator: Louise O'Regan, Occupational Therapist, Beaumont Hospital. Tel: 01 8774954 / 01 8003327

Research Supervisor: Dr. Helen French, Royal College of Surgeons in Ireland. Contact email: hfrench@rcsi.ie.

You are being invited to take part in a clinical research study to be carried out at Beaumont Hospital. Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

The purpose of this study is to look at the difficulties you are experiencing since your stroke in relation to your thinking, memory and physical abilities. Through completing this study it allows occupational therapists to ensure we are providing the best treatment to our patients.

Who is organising and funding this study?

Louise O'Regan, an Occupational Therapist in Beaumont Hospital, is carrying out this study. Professor David Williams, Consultant Geriatrician in Beaumont Hospital is co-investigator on this study and Dr. Helen French, Lecturer in Physiotherapy in the Royal College of Surgeons in Ireland is supervising the overall project. This study is part of a Master's Degree research project.

Why am I being asked to take part?

You have been invited to take part as you were admitted to Beaumont Hospital to improve your function and ability to do everyday tasks after your stroke. We are interested in hearing your opinion into the difficulties you are experiencing since your stroke.

How will the study be carried out?

Once you start your rehabilitation, you will be invited to participate in a one-off assessment. The complete study will take place over eight months and will start in September 2015 and will continue until April 2016. During this time we hope to assess 30 volunteers in the Occupational Therapy Department of Beaumont Hospital. If you decide not to take part in the study, it will not affect your care whilst in Beaumont Hospital.

What will happen to me if I agree to take part?

If you agree to participate, you will be asked some personal details and how you feel about your health and confidence in carrying out certain tasks. Assessments of your thinking and memory and your ability to complete your daily activities will be carried out, including preparing a cup of tea. This session should take on average 30 - 45 minutes and if you become tired during the assessment you can take regular rests.

What other treatments are available to me?

If you decide not to take part in the study, you will continue to be seen as normal by your occupational therapist.

What are the benefits?

There may be no direct benefit to you by taking part in this study however there may be benefit for future patients if this study results in a better assessment being used in Beaumont Hospital.

What are the risks?

If you feel upset or uncomfortable when discussing how your stroke has affected you, the test will be stopped and only continued if you wish to do so. As part of one of the assessments, you will be asked to prepare a cup of tea. There may be a slight risk of spilling boiling water, while carrying out the task. However this is not a concern as the researcher will be monitoring you very closely as you complete this assessment.

What if something goes wrong when I'm taking part in this study?

If you experience any problems when you are in the study, Louise O'Regan will be responsible for contacting your consultant to inform them.

Is the study confidential?

If you agree to participate, you will be asked some personal details about how you feel about your health and confidence in carrying out certain daily tasks. Your medical chart will be looked at to gather details of your medical background and a copy of your consent form will be placed in your chart by the principle investigator Louise O'Regan. This is part of routine assessment. When you enter the study you will be assigned a study number and from then only this number will be used to identify you on study paper. Your identity will remain confidential. Your name will not appear on the assessment forms or be disclosed to anyone else. Written information will be kept for 5 years in a safe secure location and then destroyed by shredding paper files. The computer records will be stored on a password protected encrypted computer and will contain numbered identity only and will be kept for future reference.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name: Louise O'Regan
Address: Occupational Therapy Dept., Beaumont Hospital, Beaumont Road, D9.
Phone No: 01 8774954 available 08.30 – 16.30.

Name: Department of Geriatric and Stroke Medicine
Address: Beaumont Hospital, Beaumont Road, Dublin 9
Phone No: 01 8093281

APPENDIX 2A: ETHICS APPLICATION FORM

STANDARD APPLICATION FORM

For the Ethical Review of

Health-Related Research Studies, which are not Clinical Trials of Medicinal Products for Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM

IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: Relationship between self-awareness and cognitive and functional performance post stroke: A cross-sectional study.

Application Version No: Number THREE

Application Date: 06th November 2015

For Official Use Only – Date Stamp of Receipt by REC:

This Application Form is divided into Sections.

***Sections A, B, C, D, E, J and K are Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to Section I within the form before any attempt to complete the Standard Application Form. Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

A1 TITLE OF THE RESEARCH STUDY:

Relationship between self-awareness and cognitive and functional performance post stroke: A cross-sectional study.

A2 (a) Is this a multi-site study? No

A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.

Title	**Name**	**Qualifications**	**Position**	**Department**
Ms	Louise O'Regan	BSc (Hons) (Occ. Therapy)	Occupational Therapist, Stroke Service, Beaumont Hospital	Occupational Therapy Department
Organisation	Address	Direct Telephone No.	E-Mail	Role in Research
Beaumont Hospital	Beaumont Road, Dublin 9	01 – 8528323	louiseoregan@beaumont.ie louisemoregan@rcsi.ie	Principal Investigator

A2 (f) For single-site studies, please name the only site where this study will take place.

Beaumont Hospital incorporating St. Joseph's Hospital Raheny

A3. DETAILS OF CO-INVESTIGATORS:

Title	**Name**	**Qualifications**	**Position**	**Department**
Professor	David Williams	MRCPI Consultant Stroke Physician	Consultant Stroke Physician at Beaumont Hospital and Associate Professor in Geriatric and Stroke Medicine	Department of Geriatric and Stroke Medicine
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Beaumont Hospital	Beaumont Road, D9	01 – 7974791	davidwilliams@beaumont.ie	Co-Lead Investigator

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Professor	Anne Hickey	PhD, AFPsSI, Reg.Psychol. PsSI	Head of Department of Psychology, Royal College of Surgeons	School of Psychology
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Royal College of Surgeons in Ireland	123 St. Stephen's Green, D2	01-402-2433	ahickey@rcsi.ie	Co-Lead Investigator

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Dept**
Ms	Deirdre Armitage	BSc. (Hons) (Curr Occ)	Senior Occupational Therapist, Stroke Service	Dept. of Occupational Therapy
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Beaumont Hospital	Beaumont Road, D9	01 – 8528323	Deirdrearmitage@beaumont.ie	Gatekeeper

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Ms	Alison Enright	BSc. (Hons) Occupational Therapy	Occupational Therapy Manager	Department of Occupational Therapy
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Beaumont Hospital	Beaumont Road, D9	01 – 8093327	alisonenright@beaumont.ie	Gatekeeper

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Dr.	Alan Martin	MD FRCPI Consultant Geriatrician and General Physician	Consultant in Geriatric Medicine and Honorary Senior Clinical Lecturer in RCSI	Geriatric and Stroke Medicine,
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Beaumont Hospital	Beaumont Road, Dublin 9	01 – 8092370	alanmartin@beaumont.ie	Co-investigator

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Dr.	Alan Moore	MD FRCPI Consultant Geriatrician and General Physician	Consultant in Geriatric Medicine and Honorary Senior Clinical Lecturer in RCSI	Geriatric and Stroke Medicine, Associate Clinical Director, Medical Directorate
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Beaumont Hospital	Beaumont Road, Dublin 9	01 – 8092370	mooreteam@beaumont.ie	Co-investigator

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Dr	Helen French	PhD (NUI, RCSI), B. Physio, MSc. Physio, Dup. Stat (TCD), MISCP	Lecturer in Physiotherapy, Royal College of Surgeons	School of Physiotherapy
Organisation	**Address**	**Direct Telephone No.**	**E-Mail**	**Role in Research**
Royal College of Surgeons in Ireland	123 St. Stephen's Green, Dublin 2	Tel: 01 – 4022258	hfrench@rcsi.ie	Academic Supervisor

Other Investigators (details of each Co-Investigator)

Title	**Name**	**Qualifications**	**Position**	**Department**
Dr	Tadhg Stapleton	PhD, MSc (Rehabilitation and Research), BSc (Hons) (Curr. Occ), Dip Stat	Assistant Professor	School of Occupational Therapy
Organisation	**Address**	**Direct Telephone No. and E-mail**	**E-Mail**	**Role in Research**
Trinity College Dublin	Trinity Centre, St. James Hospital, James Street,	01 - 8963214	Tadhg.stapleton@tcd.ie	Academic Advisor

	Dublin 8			

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Name & Position	**Organisation**	**Address for Correspondence**	**Direct Telephone No. &** **Mobile No.**	**Email**
Louise O'Regan, Occupational Therapist, Stroke Service	Occupational Therapy Department, Beaumont Hospital.	Occupational Therapy department, Beaumont Hospital, Beaumont Road, Dublin 9.	Tel (Work): 01 – 5828323 Tel (mob): 087 – 9063701	louiseoregan@beaumont.ie louiseoregan@rcsi.ie

A5 (a) Is this study being undertaken as part of an academic qualification? Yes

A5 (b) **IF YES**, please complete the following:

Student Name	Academic Course	Academic Institution
Louise O'Regan	Master of Science in Neurology and Gerontology	Royal College of Surgeons in Ireland

A5 (c) Academic Supervisor(s):

Title	**Name**	**Qualifications**	**Position**
Dr.	Helen French	PhD (NUI, RCSI), B. Physio, MSc. Physio, Dup. Stat (TCD), MISCP	Lecturer in Physiotherapy
Department	**Organisation**	**Address**	**Direct Telephone No. and E-mail**

School of Physiotherapy	Royal College of Surgeons in Ireland	Physiotherapy Department, 123 St. Stephen's Green, Dublin 2	Tel: 01 – 4022258 E-mail: hfrench@rcsi.ie

SECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. What is the anticipated start date of this study?

September 2015

B2. What is the anticipated duration of this study?

Eight Months – Data Collection from September 2015 – April 2016

B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

The purpose of this study is to look at the problems experienced by stroke patients in relation to thinking, memory and physical abilities and their ability to participate in activities of daily living. The study is interested in learning about the personal experiences of individuals post stroke and the difficulties experienced in relation to daily tasks.

B4. Provide brief information on the study background.

Awareness is the key to successful stroke rehabilitation and in practice poor knowledge of self-awareness and failure to recognise acute stroke deficits hinders efforts in the rehabilitation of patients. Stroke is associated with both motor and cognitive impairment, but the individual correlation between impairment, daily activities and self-awareness of deficit of stroke patients in the acute environment has yet to be explored. Although unawareness is often transient, its occurrence at the crucial acute stages can considerably impede rehabilitation and thus impact on the overall pathway of patients. A greater understanding of the relationship between self-awareness and cognitive and motor performance in the acute rehabilitation setting is necessary to enhance clinical decision-making concerning the need for awareness interventions and the possibility of tailoring therapeutic approaches according to individual circumstances.

B5. List the study aims and objectives.

Aim:

The primary aim of this research is to examine the relationship between self-awareness of disability and cognitive and functional performance in the acute stroke population.

Objectives:

1) To assess the unawareness of deficit profile in a sample of first event stroke patients in the acute phase of illness.

2) To assess the relationship between awareness of deficit and activities of daily living (ADL) cognitive ability.

3) To assess the relationship between awareness of deficit and ADL functional ability.

B6. List the study endpoints / measurable outcomes (if applicable).

Research Instruments include:

1) The Scandinavian Stroke Severity Scale (Appendix 1)

2) The Montreal Cognitive Assessment (Appendix 2)

3) The Frontal Assessment Battery (Appendix 3)

4) The Modified Barthel Index (Appendix 4)

5) The Self-Regulated Skills Interview (Appendix 5)

6) The Kettle Test (Appendix 10)

B7. Provide information on the study design.

This is a cross sectional observational study.

B8. Provide information on the study methodology

The main purpose of this observational study is to look at the relationship between self-awareness and cognitive and functional performance in acute and sub-acute stroke patients. A number of clinical measures are currently used in practice with patients post stroke including the Montreal Cognitive Assessment (MoCA). If a scoring of 17/30 or above has been achieved on the MoCA, the patient will then be approached to participate in the study i.e once the patients' ability to provide consent is confirmed;

they will be approached to participate in the study. Thus all acute stroke patients consecutively referred to occupational therapy who can provide consent to participate will be approached to participate in the study. Once written consent has been received, data collection for this observational study will commence. Demographic and baseline information will be obtained from the participant's medical chart by the primary investigator (PI). This information will include age, gender, site of stroke lesion, treatment of stroke, number of co-morbidities, current medications and details of living situation and recorded on the data collection form (Appendix 6). Following this the following measures will be completed:

1) Scandinavian Stroke Severity Scale,

2) The Modified Barthel Index (MBI).

3) The Frontal Assessment Battery (FAB)

4) The Kettle Test

Instructions will be read aloud prior to the test. The assessment procedure will take approximately 30 - 45 minutes to complete. Providing impairment has been identified in cognitive or functional ability, the Self-Regulation Skills Interview (SRSI) will be completed by the primary investigator.

B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

Statistical Package for the Social Sciences (SPSS) for statistical analysis version 21.0 will be used to analyse the data. Data will be examined for correlations between self-awareness and cognitive ability and self-awareness and functional ability. Descriptive statistics including mean, standard deviation and confidence intervals will be derived for continuous variables including baseline demographics and clinical evaluations of the group using parametric and non-parametric methods as appropriate. The significance of correlation in the SRSI and cognitive and functional measures will be calculated using the Spearman Rho correlation analysis for non-parametric data. Statistical analysis will be completed with the RCSI statistician.

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference)

The applicant has liaised with Professor Ronan Conroy, RCSI statistician. The sample size has calculated using Ronan Conroy's sample size guide. Based on this guide, a sample of 30 patients would give the study approximately a 90% power to detect a correlation of 0.55. Therefore, a sample size of 30 participants has now been chosen for this study.

B11. How many research participants are to be recruited in total?

Thirty participants

B12 (b) Please provide details on the method of randomisation (where applicable).

NON-APPLICABLE

SECTION C STUDY PARTICIPANTS

SECTION C IS MANDATORY

C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 HOW will the participants in the study be selected?

Consecutive patients with a diagnosis of stroke will be recruited from inpatients in Beaumont hospital, incorporating St Joseph's hospital Raheny. Recruitment will take place over an eight month period between September 2015 and April 2016. All Consultant Geriatricians in Beaumont Hospital have been informed of the study aims and objectives.

C1.2 HOW will the participants in the study be recruited?

The selection criterion will be applied to all newly diagnosed Stroke patients admitted to Beaumont hospital. Eligible participants will be invited to enrol in the study by the gatekeeper (Appendix 7) and provided with an information leaflet (Appendix 8) detailing the purpose and nature of the study. All participants will be required to participate voluntarily and provide written informed consent (Appendix 9). All participant information will have been pre-approved by the National Adult Literacy Agency (NALA) to ensure appropriate use of language for this population group.

Participants will be made aware of their ethical right to withdraw from the study without giving reason or personal consequences. The participant will be given a 48-hour period of time to allow comprehension of the information provided. Assessment will take place following this. Should a participant be discharged before full assessment has been completed, they will be invited to return to the occupational therapy department to complete the assessment.

C1.3 What are the inclusion criteria for research participants?

Inclusion criteria:

1) Clinical diagnosis of first time Stroke (Time-period: within 90 days of acute-stroke)

2) Able to provide written informed consent (MoCA scoring of 17/30 or above)

3) Medically stable

4) Able to participate in the assessment procedure

5) Residual cognitive or perceptual or functional deficits present post stroke

C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

Exclusion criteria:

1) Patients who are unable to provide informed consent to participate in the study

2) Severe communication problems and/or inability to comply with simple instructions

3) Evidence of post-stroke delirium or disorientation

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project?

Not to my knowledge

C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

Consent will be requested by the researcher when the patient is satisfied that he/she has received all the necessary information required to make the decision whether to participate or not and has been allowed the sufficient time requested to consider the matter.

If the patient agrees to participate in the project, he/she will then be asked to sign a consent form.

If the patient does not wish to participate, an appreciation is to be shown for their time given and no further details about the research will be discussed with the patient or their family.

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?

Yes, this will be clearly outlined during first contact with the patient. This information is also outlined in the Patient Information Leaflet.

C2.3 (a) Will there be a time interval between giving information and seeking consent?

Yes

C2.3 (b) If yes, please elaborate.

A 48-hour period will be provided to patients to allow comprehension of the information provided prior to seeking written consent. This will provide sufficient time to allow patients to discuss the study with family members and for the PI to satisfy any questions highlighted by patients or their families.

C3 Adult participants (AGED 18 or over) - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? Yes, the medical and further multidisciplinary team members managing and providing the patients care will be able to identify those patients deemed incapable of providing accurate factual information. If the patient is not able to give fully informed consent and is incapable of providing accurate factual information, the researcher will return to see the patient at a later date when further

recovery is likely to take place. If a patient is deemed cognitively not capable by the medical staff, they will not be approached to participate.

C4 Participants under the age of 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

C5 PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5. Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients Yes

Unconscious patients No

Current psychiatric in-patients No

Patients in an emergency medical setting No

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships No

Students No

Employees / staff members No

Persons in residential care Yes

Persons highly dependent on medical care No

(e) Intellectually impaired persons No

(f) Persons with a life-limiting condition Yes

(g) Persons with an acquired brain injury Yes

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

1) Persons who are admitted to Beaumont Hospital from residential care will not be excluded from this study as it is an observational study of awareness of deficits post stroke which apply to all population groupings. If the patient meets the inclusion criteria and can provide informed verbal and written consent to participate in the study, they will be considered appropriate to participate. No increased vulnerability for this population grouping is detected.

2) This study focuses on patients with the acquired brain injury of stroke. All participants will be required to meet the inclusion criteria as highlighted above and be able to provide informed verbal and written consent to participate in the study.

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

Yes, however this study will not include any intervention so these patients are not at risk of any adverse effects.

SECTION D RESEARCH PROCEDURES

SECTION D IS MANDATORY

D1 (A) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

Occupational Therapy Assessment on admission, with a view to eligibility for recruitment. If the patient meets the inclusion criteria and provides informed consent, the data collection will commence. If the patient is discharged from inpatient services before full assessment is completed, they will be invited to return to Beaumont occupational therapy department for assessment as an outpatient. Consent will have been received pre-discharge. Two research instruments proposed for use are performed as part of usual occupational therapy care.

1) The Montreal Cognitive Assessment (MoCA)

2) The Modified Barthel Index (MBI)

If impairment has been identified in cognitive or functional domains in the above assessments, the following assessments will be completed:

1) The Scandinavian Severity Scale

2) The Frontal Assessment Battery

3) The Kettle Test

4) The Self-Regulation Skills Interview (SRSI)

Instructions will be read aloud prior to the test. The assessment procedure will take approximately 30 - 45 minutes to complete.

D1 (b) What other activities (if any) are taking place for the purposes of this research study e.g. chart review, sample analysis etc?

Demographic and baseline information will be obtained from the participant's medical chart by the PI. This information will include age, gender, site of stroke lesion, treatment of stroke, number of co-morbidities, current medications and details of living situation and recorded on the data collection form (Appendix 5).

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

There is a very slight risk that participants could become distressed when completing the interview, the process will be discontinued if this becomes apparent.

There is also a very slight risk that participants could lose their balance during the MBI and the kettle assessment. However this is very unlikely as all participants will be supervised very closely at all times.

D3. What is the potential benefit that may occur as a result of this study?

There may be no direct benefit to patients by taking part in this study however there may be benefit for future patients if this study results in a better multidisciplinary assessment being used in Beaumont Hospital.

D4 (a) Will the study involve the withholding of treatment?

No

D4 (b) Will there be any harms that could result from withholding treatment?
No

D5 (a) How will the health of participants be monitored during the study, and who will be responsible for this?

Standard protocols are already in place for all patients attending the occupational therapy department. Should an adverse event occur the relevant and appropriate medical, nursing and multi-disciplinary team members will be informed and an incident report form will be completed in line with current practice. It is the responsibility of the investigator, Louise O'Regan, to report immediately in writing to the Research Ethics Committee.

D5 (b) How will the health of participants be monitored after the study, and who will be responsible for this?

The participants will be under Medical care provided by Beaumont Hospital as an inpatient or outpatient at all times during and after this study.

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study? Non-applicable

D7. Please comment on how individual results will be managed.

Individual results will be recorded in the medical chart as this is already part of standard practice. All results of assessments will be given and explained to the participants. As this is an observational study, it is not anticipated that new information that will impact on their initial consent will become available. Individual data will be collected and subsequently coded and transferred to an Excel spreadsheet and stored on a password protected computer.

D8. Please comment on how aggregated study results will be made available.

This research protocol forms part of a Master's Degree in Neurology and Gerontology and will be reported in a dissertation by the principle investigator. Study results may also be disseminated through published research or conference presentations.

D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)? No

D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)? Yes

SECTION E DATA PROTECTION

SECTION E IS MANDATORY

E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes

E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?

The principal investigator, gatekeeper and supervisor will have access to the data and to a separate excel file which will link the codes to the participants. Electronic records will be stored on a secure encrypted memory stick and a password protected desktop in Beaumont Hospital. Paper records and the encrypted memory stick will be stored in a locked cabinet in the Occupational Therapy Department at Beaumont hospital. Data will be stored securely for five years.

E2.2 What media of data will be collected?

Data will be initially recorded on paper forms and then transcribed to an electronic database.

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

Coded – Each participant will be given a unique code in order to uphold patient confidentiality. This will then be the only identifiable marker on all record sheets and electronic records.

E2.3 (b) If 'coded', please confirm who will retain the 'key' to re-identify the data?

The principle investigator and the project supervisor will have access to the separate excel file which will link the codes to the participants.

E2.4 Where will data which is collected be stored?

All paper records and the encrypted memory stick with the encoded data will be stored in a locked cabinet in the Occupational Therapy department at Beaumont hospital. The principle investigator will hold the key to the cabinet, with data stored securely for five years.

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.

The data collected will be stored under the Data Protection Act (2003) and the Data Guidance on Research in Health Sector (2007). Paper records and the encrypted memory stick will be stored in a locked cabinet in the Occupational Therapy department. Electronic records will be stored on a secure encrypted memory stick and a password protected desktop in Beaumont Hospital.

E2.6 (a) Will data collected be at any stage leaving the site(s) of origin? No

E2.7 Where will data analysis take place and who will perform data analysis (if known)?

Data analysis will take place in Beaumont Hospital by the principle investigator.

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Coded data will be stored securely for five years.

E2.8 (b) Please elaborate.

Paper data will be shredded and electronic data destroyed after five years.

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

The paper data will be shred by the primary investigator on-site after five years.

Electronic data will be destroyed.

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Coded data will be stored securely for five years

E2.9 Please comment on the confidentiality of collected data.

Each participant will be given a unique code in order to uphold patient confidentiality. This will then be the only identifiable marker on all record sheets and electronic records. The principal investigator and the supervisor will have access to a separate excel file which will link the codes to the participants. All electronic records will be stored on a secure encrypted memory stick and a password protected desktop in Beaumont Hospital. Paper records and the encrypted memory stick will be stored in a locked cabinet in the Occupational Therapy Department at Beaumont Hospital.

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings? No

E2.11 (a) Will any of the study data collected consist of photographs/video recordings? No

E3 ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? Yes

If answer is No, please delete remaining questions in Section E3

E3.1 (b) If yes, please elaborate.

Demographic and baseline information will be obtained from the participant's medical chart by the PI.

E3.1 (c) Who will access these healthcare records?

The principle investigator and the gatekeeper.

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? Yes

E3.2 (a) Who or what legal entity is the data controller in respect of the healthcare records? Beaumont Hospital

E3.2 (b) What measures have been put in place by the data controller which may make access to healthcare records permissible without consent? Non-applicable

SECTION F HUMAN BIOLOGICAL MATERIAL

F1 Bodily Tissue / Bodily Fluid Samples - general

F1 1 (a) Does this study involve human biological material? NO

SECTION G RADIATION

G1 Radiation - General

G1.1 (a) Does this study/trial involve exposure to radiation? NO

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? NO

SECTION I COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

SECTION J INDEMNITY and INSURANCE

SECTION J IS MANDATORY

J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.

The Principal Investigator is an employee of Beaumont Hospital and is covered by the hospitals Clinical Indemnity scheme.

J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.

All investigators are employed by Beaumont Hospital and are covered by the hospitals Clinical Indemnity scheme. Co-investigators are covered by their academic institutional indemnity.

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

The principle investigator is an employee of Beaumont Hospital and is covered by the hospitals clinical indemnity scheme.

Name: Louise O'Regan,

Address: Occupational Therapy Department, Beaumont Hospital, Beaumont Road, Dublin 9.

J3.2 Where an organisation is legally responsible, please specify if this organisation is:

NON-APPLICABLE

J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?

This research protocol forms part of a Master's Degree in Neurology and Gerontology from the Royal College of Surgeons of Ireland. The primary investigator is also covered by the indemnity provided by RCSI.

SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

K1 COST AND RESOURCE IMPLICATIONS

K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)

Administration Fees: The projected photocopying costs of assessments are 36.00 euro in total. This accounts for the six sheets required per participant at 15c per sheet. All costs will be incurred by the primary investigator.

K2 FUNDING

K2.1 (a) Is funding in place to conduct this study? NO

K2.1 (b) If no, has funding been sought to conduct this study? NO

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? NO

K3 PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? NO

K4 PAYMENTS TO PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? NO

SECTION l ADDITIONAL ETHICAL ISSUES

L1 (a) Does this project raise any additional ethical issues? NO

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

APPENDIX 2B: ETHICS APPROVAL FORM

Royal College of Surgeons in Ireland
The Research Ethics Committee
121 St. Stephens Green, Dublin 2, Ireland.
Tel: +353 1 4022205 Email: recadmin@rcsi.ie

RCSI
ROYAL COLLEGE OF SURGEONS IN IRELAND
COLÁISTE RÍOGA NA MÁINLEA IN ÉIRINN

Dr David Smith, Acting Chair
Dr Niamh Clarke, Convenor

21st October 2015

Ms Louise O'Regan
Occupational Therapy Department
Beaumont Hospital
Beaumont Road,
Dublin 9

Ethics Reference No:	REC 1159 (accepted approval from Beaumont Hospital REC)
Project Title:	Relationship between self-awareness and cognitive and functional performance in acute stroke: A cross-sectional study.
Researchers Name (lead applicant & PI):	Ms Louise O'Regan (Occupational Therapy Department, Beaumont hospital)
Other Individuals Involved:	Prof David Williams (Department of Geriatric and Stroke Medicine Beaumont Road); Prof Anne Hickey (RCSI School of Psychology); Dr Helen French (academic supervisor, RCSI School of Physiotherapy)

Dear Ms O'Regan,
Thank you for your Research Ethics Committee (REC) application. The RCSI HREC accepts the ethical approval granted by Beaumont Hospital REC for the research study (details above) submitted by Ms Louise O'Regan.

This letter provides approval for data collection for the time requested in your application and for an additional 6 months. This is to allow for any unexpected delays in proceeding with data collection. Therefore this research ethics approval will expire on **19th November 2016.**

Where data collection is necessary beyond this point, approval for an extension must be sought from the Research Ethics Committee.

This ethical approval is given on the understanding that:

- All personnel listed in the approved application have read, understand and are thoroughly familiar with all aspects of the study.
- Any significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the REC, and an ethical amendment submitted where appropriate.
- Please submit a final report to the REC upon completion of your project.

We wish you all the best with your research.

Yours sincerely,

Niamh Clarke

PP Dr Niamh Clarke (Convenor)
Dr David Smith (Acting Chair)

APPENDIX 2B: ETHICS APPROVAL FORM

Ethics (Medical Research) Committee - Beaumont Hospital
Notification of ERC/IRB Approval

Principal Investigator: Ms. Louise O'Regan (Occ. Therapist)

Consultant co-investigator: Prof. D. Williams

REC reference: 15/75

Protocol Title: Relationship between self-awareness and cognitive and functional performance in acute stroke: a cross-sectional study

Ethics Committee Meeting Date: 27th August 2015

Final Approval Date: 25th September 2015

From: Ethics (Medical Research) Committee - Beaumont Hospital, Beaumont, Dublin 9

Documents Reviewed

Document and Date	Date Reviewed	Approved
Application Form, V2, 21/9/15	25/9/15	Yes
Study Summary, no version no.	25/9/15	Yes
Gatekeeper Consent Form, no version no.	25/9/15	Yes
Patient Information Leaflet, V2, 21/9/15	25/9/15	Yes
Patient Consent Form, no version no.	25/9/15	Yes
Assessments: -		
Frontal Assessment Battery	25/9/15	Yes
Self-Regulated Skills Interview (SRSI)	25/9/15	Yes
Data Collection Form, no version no.	25/9/15	Yes
CV: L.O'Regan, 11/8/15	25/9/15	Noted
CV: D. Williams, 11/8/15	25/9/15	Noted

Dr. Peter Brannigan
ERC/IRB Convenor's Signature
Approval # 1, dated 25 September 2015

APPENDIX 3A: ETHICAL AMENDMENT LETTER

LETTER FOR THE SUBMISSION OF AN AMENDMENT

Date: 06/11/2015

Chairperson, Ethics (Medical Research) Committee,
Beaumont Hospital,
Dublin 9.

Ethics Committee Reference Number: 15 / 75
Principal Investigator: Ms. Louise O'Regan
Title of Study: Relationship between self-awareness and cognitive and functional performance post stroke: A cross-sectional study.
Amendment Number: # 01
Date of Amendment: 06 / 11 / 2015

Dear Chairperson

I would like to make an amendment to the above-named application. I would like to add in another outcome measure, called 'The Kettle Test'. This test is a brief performance-based assessment of domestic activities of daily living. It assesses a broad range of cognitive skills within a functional context.

The rationale for this amendment is:

The primary aim of this research is to examine the relationship between self-awareness of disability and cognitive and functional performance in the sub-acute stroke population. I have piloted the study with three patients using the approved outcome measurement tools. The tools that I am currently approved to complete do not assess self-awareness beyond personal activities of daily living thus not truly examining the relationship between awareness of disability and functional performance. For this reason, I believe that the introduction of a functional measure that assesses cognitive and functional performance in relation to instrumental activities of daily living would enrich the information gathered. This test takes between 5 – 15 minutes to administer. Functional kitchen assessments are often a component of 'usual' care / assessment for patients in the acute / sub-acute setting. If this test is administered as part of this research study, there will be no further need to complete a functional kitchen assessment for the patient involved. The purpose of this study is to look at the problems experienced by stroke patients in relation to thinking, memory and their ability to participate in activities of daily living. The basic task of preparing a hot beverage has functional significance for this population group and is feasible to complete in the hospital setting. The total time required to complete the session will be approximately 30 – 45 minutes.

I enclose the following documents for review.

Enclosures:

1) Details of the Kettle Test
2) Updated Patient Information Leaflet (Highlighted Changes)
3) Updated Application Form (Highlighted Changes)

Yours sincerely

_____

Louise O'Regan
Occupational Therapist
Beaumont Hospital
Tel: 01 8774954 / 087 9063701

APPENDIX 3B: ETHICAL AMENDMENT APPROVAL FORM

Royal College of Surgeons in Ireland
The Research Ethics Committee
121 St. Stephens Green, Dublin 2, Ireland.
Tel: +353 1 4022205 Email: recadmin@rcsi.ie

RCSI
ROYAL COLLEGE OF SURGEONS IN IRELAND
COLÁISTE RÍOGA NA MÁINLEA IN ÉIRINN

Dr David Smith, Acting Chair
Dr Niamh Clarke, Convenor

18th January 2016

Ms Louise O'Regan
Occupational Therapy Department
Beaumont Hospital
Beaumont Road,
Dublin 9

Ethics Reference No:	REC 1159b (accepted approval from Beaumont Hospital REC)
Project Title:	Relationship between self-awareness and cognitive and functional performance in acute stroke: A cross-sectional study.
Researchers Name (lead applicant & PI):	Ms Louise O'Regan (Occupational Therapy Department, Beaumont hospital)
Other Individuals Involved:	Prof David Williams (Department of Geriatric and Stroke Medicine Beaumont Road); Prof Anne Hickey (RCSI School of Psychology); Dr Helen French (academic supervisor, RCSI School of Physiotherapy)

Dear Ms O'Regan,
Thank you for your Research Ethics Committee (REC) amendment application. The RCSI HREC accepts the ethical approval granted by Beaumont Hospital REC for the amended research study (details above) submitted by Ms Louise O'Regan.

Content of Amendment:

- Amended Patient Information Leaflet regarding addition of the Kettle Test to the study.

This letter provides approval for data collection for the time requested in your application and for an additional 6 months. This is to allow for any unexpected delays in proceeding with data collection. Therefore this research ethics approval will expire on **19th November 2016.**

This ethical approval is given on the understanding that:

- All personnel listed in the approved application have read, understand and are thoroughly familiar with all aspects of the study.
- Any significant change which occurs in connection with this study and/or which may alter its ethical consideration, must be reported immediately to the REC, and an ethical amendment submitted where appropriate.
- Please submit a final report to the REC upon completion of your project.

We wish you all the best with your research.

Yours sincerely,

Niamh Clarke

PP Dr Niamh Clarke (Convenor)
Dr David Smith (Acting Chair)

APPENDIX 3B: ETHICAL AMENDMENT APPROVAL FORM

Suíomh Gréasáin: Website: www.beaumont.ie

OSPIDÉAL BEAUMONT
Bosca O.P. 1297 Bóthar Beaumont Baile Átha Cliath 9

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Guthán: Telephone: 8093000 / 8377755 Facs: Facsimile: 837 6982

Beaumont Hospital Research Ethics Committee

Chairperson: Professor NG McElvaney
Convenor: Dr Peter Branagan

Administrator: Ms Maria Mahoney

30th November 2015

Dear Ms O'Regan

Re: Study 15/75 Relationship between self-awareness and cognitive and functional performance post stroke: a cross-sectional study.

We can confirm we have received the Amended Patient Information Leaflet regarding addition of the Kettle Test to the study.

The Beaumont Hospital Research Ethics Committee has approved this amendment and are happy for the Study to proceed as planned.

We apologise for the delay in correspondence, due to unforeseen circumstances the Beaumont Hospital Research Ethics Committee is currently without Administrative support.

Yours sincerely,

Dr Peter Branagan
Convenor
Beaumont Hospital Research Ethics Committee

APPENDIX 4: PATIENT CONSENT FORM

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

Patient Consent Form

STUDY TITLE: Relationship between self-awareness and cognitive and functional performance post stroke: A cross-sectional study.

I have read and understood the Information Leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	Yes □	No □
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	Yes □	No □
I am aware of the potential risks of this research study.	Yes □	No □
I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.	Yes □	No □
I have been given a copy of the Information Leaflet and this completed consent form for my records.	Yes □	No □
Storage and future use of information: I give my permission for information collected about me to be stored or electronically processed for the purpose of scientific research and to be used in <u>related studies or other studies in the future</u> but only if the research is approved by a Research Ethics Committee.	Yes □	No □

Patient Name (Block Capitals) | Patient Signature | Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals) | Qualifications | Signature | Date

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.

APPENDIX 5: THE KETTLE TEST

The Kettle Test

Task: Prepare two cups of hot beverage

Step	Score (0-4)	Comments
1) Opening the water faucet		
2) Filling the kettle with about 2 cups of water		
3) Turing off the faucet		
4) Assembling the kettle		
5) Attaching the electric cord to the kettle		
6) Pluggin the electric cord in an electric socket		
7) Turning on the kettle		
8) Assembling the ingredients		
9) Putting the ingredients into the cups		
10) Picking up the kettle when water boils		
11) Pouring the water into the cups		
12) Adding milk		
13) Indication of task completion (e.g. verbal, gesture, serving)		
Total Score (0-52)		

Scoring:

Rating of performance on the thirteen steps of the task. Each step scored 0-4:
0 - Intact performance
1 - Slow and/or trial & error, and/or questionable performance, but completes independently
2 - Received general cues
3a) Received specific cueing:
b) incomplete performance (for example, puts only part of the ingredients in the cups, lifts the kettle before the water boils etc.) or deficient performance (for example, puts cover upside down, uses wrong ingredients; or c. did not perform (omitted a step, for example did not turn on the kettle, did not put milk etc.)
4 - Received physical demonstration or assistance. Total score 0-52, higher scores reflecting more severe problems in performance.

Following performance:

The examiner notes the process that took place and after that asks the client to recall the instructions and the process, to rate his/her performance and the level of difficulty he/she experienced in performing the task.

Description of the process by the examiner:

_____
_____
_____

Recall of the instructions by the client: “what were the steps you had to do”?

_____
_____
_____

The client’s description of the process: “describe to me what you did from the beginning to the end of the task.

_____
_____
_____

Rating of performance by the client: “how do you rate your performance on this task between 0 to 100%?” (if the client cannot rate his/her performance then suggest the following options: “very good”, “fair”, “not so good”, “not good at all”).

_____
_____
_____

Rating of difficulty by the client: “how difficult was the task for you? easy (able to do by yourself easily); a little difficult or very difficult (I needed help)”.

_____
_____
_____

Additional comments:

_____
_____
_____

APPENDIX 6: SCANDINAVIAN STROKE SEVERITY SCALE

SCANDINAVIAN STROKE SEVERITY SCALE

Patient Name: _____

Rater Name: _____

Date: _____

FUNCTION	**Prognostic Score**	**Long-Term Score**	
Consciousness:			
-fully conscious	6		____
-somnolent, can be awaked to full consciousness	4		
-reacts to verbal command, but is not fully conscious	2		
Eye movement:			
-no gaze palsy	4		____
-gaze palsy present	2		
-conjugate eye deviation	0		
Arm, motor power *:			
-raises arm with normal strength	6	____	____
-raises arm with reduced strength	5		
-raises arm with flexion in elbow	4		
-can move, but not against gravity	2		
-paralysis	0		
Hand, motor power *:			
-normal strength	6		____
-reduced strength in full range	4		
-some movement, fingertips do not reach palm	2		
-paralysis	0		
Leg, motor power *:			
-normal strength	6	____	____
-raises straight leg with reduced strength	5		
-raises leg with flexion of knee	4		
-can move, but not against gravity	2		
-paralysis	0		

Orientation:			
-correct for time, place and person	6		____
-two of these	4		
-one of these	2		
-completely disorientated	0		
Speech:			
-no aphasia	10		____
-limited vocabulary or incoherent speech	6		
-more than yes/no, but not longer sentences	3		
-only yes/no or less	0		
Facial palsy:			
-none/dubious	2		____
-present	0		
Gait:			
-walks 5 m without aids	12		____
-walks with aids	9		
-walks with help of another person	6		
-sits without support	3		
-bedridden/wheelchair	0		
Maximal Score	____	22	48

*** Motor power is assessed only on the affected side.**

APPENDIX 7: MODIFIED BARTHEL INDEX

MODIFIED BARTHEL INDEX SCORING SHEET
Patient Name: _____
Rater Name: _____
Date: _____

Activity	**Score**
FEEDING 0 = unable 5 = needs help cutting, spreading butter, etc., or requires modified diet 10 = independent	_____
BATHING 0 = dependent 5 = independent (or in shower)	_____
GROOMING 0 = needs to help with personal care 5 = independent face/hair/teeth/shaving (implements provided)	_____
DRESSING 0 = dependent 5 = needs help but can do about half unaided 10 = independent (including buttons, zips, laces, etc.)	_____
BOWELS 0 = incontinent (or needs to be given enemas) 5 = occasional accident 10 = continent	_____
BLADDER 0 = incontinent, or catheterized and unable to manage alone 5 = occasional accident 10 = continent	_____
TOILET USE 0 = dependent 5 = needs some help, but can do something alone 10 = independent (on and off, dressing, wiping)	_____
TRANSFERS (BED TO CHAIR AND BACK) 0 = unable, no sitting balance 5 = major help (one or two people, physical), can sit 10 = minor help (verbal or physical) 15 = independent	_____

MOBILITY (ON LEVEL SURFACES)
0 = immobile or < 50 yards
5 = wheelchair independent, including corners, > 50 yards
10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards _____

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent _____

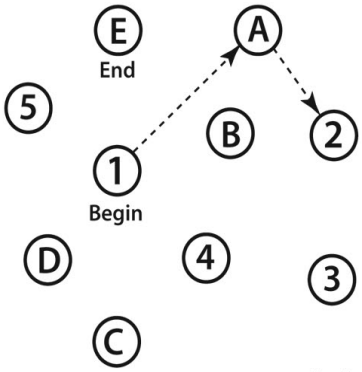
TOTAL (0–100): _____

APPENDIX 8: MONTREAL COGNITIVE ASSESSMENT

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

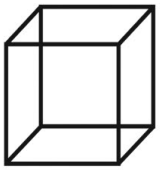
NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS



[ ] [ ]

Copy cube

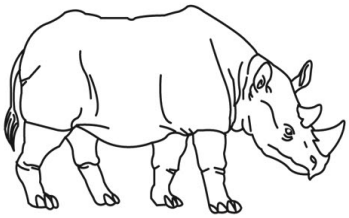


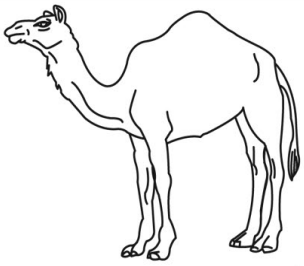
Draw CLOCK (Ten past eleven)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING





[ ] [ ] [ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4
Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]
The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUED recall only
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]	
Optional Category cue						
Optional Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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TOTAL __/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

APPENDIX 9: DATA COLLECTION FORM

Data Collection Form

Principle Investigator: Ms. Louise O'Regan, Occupational Therapist, Beaumont Hospital. Tel: 01 8528323
Supervisor: Dr. Helen French. E-mail: hfrench@rcsi.ie

Study Number:	
DOB:	**Gender: M** □ **F** □

Date of Admission:	**Date of Investigations:**
Presenting Diagnosis:	
Site of Lesion:	
Treatment of Stroke **e.g. Thrombolysis / Thrombectomy**	
MRI Brain Results:	
CT Brain Results:	
Past Medical History:	
Medications:	

Social Supports:

Lives Alone □	**Lives with Family** □	**Specify: _____**
Formal Supports □	**Informal Supports** □	**Specify: _____**

Data Collection Form	**Study Number:**

RESEARCH INSTRUMENT SCORING SHEET:

Scandinavian Stroke Severity Scale	**Prognostic Score**	**Long-Term Score**
Consciousness:	/6	
Eye movement:	/4	
Arm, motor power *:	/6	/6
Hand, motor power *:		/6
Leg, motor power *:	/6	/6
Orientation:		/6
Speech:		/10
Facial palsy:		/2
Gait:		/12
Total Scoring:	**/22**	**/48**

RESEARCH INSTRUMENT SCORING SHEET:

Montreal Cognitive Assessment	**Scoring**
Visuospatial / Executive	/5
Naming	/3
Attention	/6
Language	/3
Abstraction	/2
Delayed Recall	/5
Orientation	/6
Total Scoring:	**/30**

Data Collection Form	**Study Number:**

RESEARCH INSTRUMENT SCORING SHEET:

Frontal Assessment Battery	**Scoring**
Similarities	/3
Lexical Fluency	/3
Motor Series (programming)	/3
Conflicting Instructions (sensitivity to interference)	/3
Go–no go (inhibitory control)	/3
Prehension behaviour (environmental autonomy)	/3
Total Scoring:	**/18**

RESEARCH INSTRUMENT SCORING SHEET:

Modified Barthel Index	**Scoring**
Feeding	/10
Bathing	/5
Grooming	/5
Dressing	/10
Bowels	/10
Bladder	/10
Toilet Use	/10
Transfers (Bed to Chair and Back)	/15
Mobility (On level Surfaces)	/15
Stairs	/10
Total Scoring	**/100**

Data Collection Form	**Study Number:**

RESEARCH INSTRUMENT SCORING SHEET:

Self-Regulated Skills Interview	**Scoring**
Emergent awareness:	0 / 5 / 10
Anticipatory awareness:	0 / 5 / 10
Strategy awareness:	0 / 5 / 10
Strategy use:	0 / 5 / 10
Strategy effectiveness:	0 / 5 / 10
Total Scoring:	**/50**

Level of skills: 0 [very high] / 5 [moderate] / 10 [very low].

RESEARCH INSTRUMENT SCORING SHEET:

The Kettle Test	**Scoring**
Opening the water faucet	
Filling the kettle with about 2 cups of water	
Turing off the faucet	
Assembling the kettle	
Attaching the electric cord to the kettle	
Plugging the electric cord in an electric socket	
Turning on the kettle	
Assembling the ingredients	
Putting the ingredients into the cups	
Picking up the kettle when water boils	
Pouring the water into the cups	
Adding milk	
Indication of task completion (e.g. verbal, gesture, serving)	
Total Score (0-52)	

APPENDIX 10: FRONTAL ASSESSMENT BATTERY

CONTENT, INSTRUCTIONS, AND SCORING OF THE FAB

Name: _____

1.Similarities (conceptualization)

"In what way are they alike?"

A banana and an orange (In the event of total failure: "they are not alike" or partial failure: "both have peel," help the patient by saying: "both a banana and an orange are . . . " but credit 0 for the item; do not help the patient for the two following items)

b. table and a chair

c. A tulip, a rose and a daisy

Score: 0 (none correct)
1 (one correct)
2 (two correct)
3 (three correct)

2. Lexical fluency (mental flexibility)

"Say as many words as you can beginning with the letter 'S,' any words except surnames or proper nouns." If the patient gives no response during the first 5 seconds, say: "for instance, snake." If the patient pauses 10 seconds, stimulate him by saying: "any word beginning with the letter 'S'." The time allowed is 60 seconds.

Score (word repetitions or variations [shoe, shoemaker], surnames, or proper nouns are not counted as correct responses)

Score: 0 (< 3 words)
1 (3 - 5 words)
2 (6 - 9 words)
3 (>9 words)

3. Motor series (programming)

"Look carefully at what I'm doing." The examiner, seated in front of the patient, performs alone three times with his left hand the series of Luria "fist–edge–palm." "Now, with your right hand do the same series, first with me, then alone." The examiner performs the series three times with the patient, then says to him/her: "Now, do it on your own."

Score:
0 (Patient cannot perform three correct consecutive series even with the examiner)
1 (Patient fails alone, but performs three correct consecutive series with the examiner)
2 (Patient performs at least three correct consecutive series alone)
3 (Patient performs six correct consecutive series alone)

4. Conflicting instructions (sensitivity to interference)

"Tap twice when I tap once." To be sure that the patient has understood the instruction, a series of three trials is run: 1–1–1. "Tap once when I tap twice." To be sure that the patient has understood the instruction, a series of three trials is run: 2–2–2.

The examiner performs the following series: 1–1–2–1–2–2–2–1–1–2.

Score: 0 (Patient taps like the examiner at least four consecutive times)
1 (More than two errors)
2 (One or two errors)
3 (No error)

5. Go–no go (inhibitory control)

"Tap once when I tap once." To be sure that the patient has understood the instruction, a series of three trials is run: 1–1–1. "Do not tap when I tap twice." To be sure that the patient has understood the instruction, a series of three trials is run: 2–2–2.

The examiner performs the following series: 1–1–2–1–2–2–2–1–1–2.

Score: 0 (Patient taps like the examiner at least four consecutive times)
1 (More than two errors)
2 (One or two errors)
3 (No error)

6. Prehension behaviour (environmental autonomy)

"Do not take my hands." The examiner is seated in front of the patient. Place the patient's hands palm up on his/her knees. Without saying anything or looking at the patient, the examiner brings his/her hands close to the patient's hands and touches the palms of both the patient's hands, to see if he/she will spontaneously take them. If the patient takes the hands, the examiner will try again after asking him/her: "Now, do not take my hands."

Score: 0 (Patient takes the examiner's hand even after has been told not to do so)
1 (Patient takes the hands without hesitation)
2 (Patient hesitates and asks what he/she has to do)
3 (Patient does not take the examiner's hands)

Global score = Sum of subtest scores: _____

<u>Interpreting Results</u>

A cut off score of 12 on the FAB has a sensitivity of 77% and specificity of 87% in differentiating between frontal dysexecutive type dementias and DAT.

APPENDIX 11: SELF REGULATED SKILLS INTERVIEW (SRSI)

The Format and Questions for the SRSI.

Screening question: ‘‘Think about the various ways that you may have changed since your injury. Can you tell me one aspect of yourself that has changed which causes you the most distress and holds you back in everyday living?’’ Main area of difficulty
Emergent awareness: ‘‘Can you tell me how you know that you experience (main difficulty); that is, what do you notice about yourself?’’ Prompt: ‘‘What else might you notice?’’; ‘‘So far you’ve told me ....., is there anything else?’’
Anticipatory awareness: ‘‘When are you most likely to experience (main difficulty), or, in which situations does it mainly occur?’’ Prompt: ‘‘In what other situations would you expect more or greater (main difficulty)?’’; ‘‘So far you’ve told me ....., can you think of anything else?’’
Motivation to change:* ‘‘How motivated are you to learn some different strategies to help overcome (main difficulty)?’’ 0 1 2 3 4 5 6 7 8 9 10 ‘‘Not at all’’ ‘‘Very motivated’’
Strategy awareness: ‘‘Have you thought of any strategies that you could use to help cope with your (main difficulty)?’’ and ‘‘What are they?’’ Prompt: ‘‘What else could you try that might help?’’; ‘‘So far you’ve told me ....., can you think of any other strategies?’’
Strategy use: ‘‘What strategies are you currently using to cope with your (main difficulty)?’’ Prompt: ‘‘Can you think of anything else that you are currently using or have tried recently?’’; ‘‘So far you have said ....., are there any other strategies you are using?’’
Strategy effectiveness: ‘‘How well do the strategies that you are using for (main difficulty) work for you?’’ Prompt: ‘‘How do you know that they are helpful/unhelpful?’’; ‘‘Would you notice any difference if you stopped using the strategies?’’

* It is suggested that the phrasing of this question changes after a rehabilitation program has been completed.